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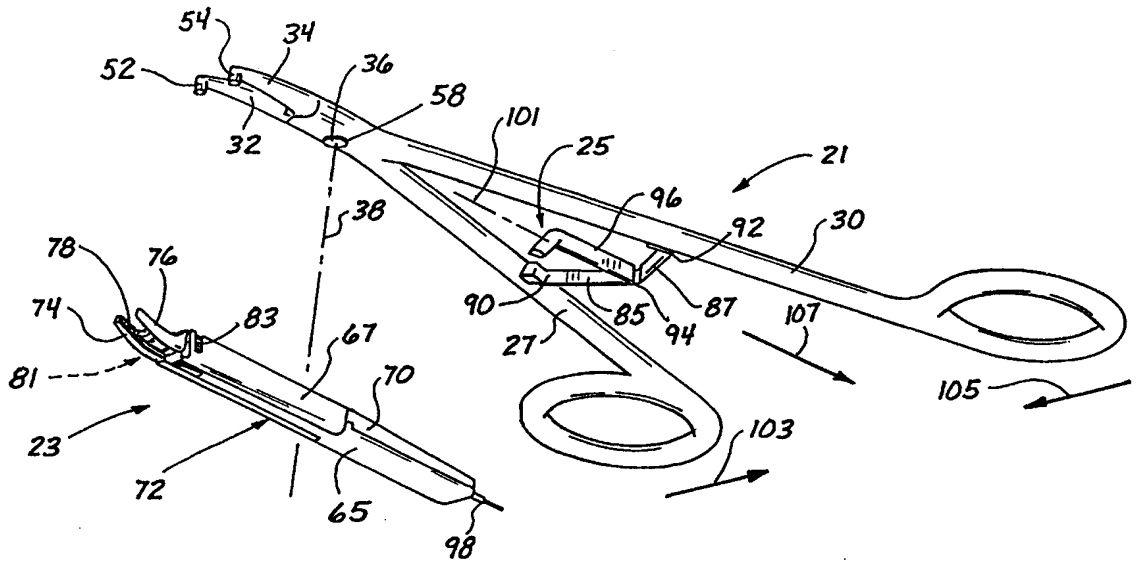

(57) Abstract

A clip applier (10) is adapted for use in positioning, and actuating a surgical clip (78) relative to body tissue. The applier includes a pair of handles (47, 50) operable by a user, and a cartridge (23) containing a plurality of clips removably attached to the handles. A pair of jaws (74, 76) are carried by the cartridge, adapted to receive, and actuate the clips by operation of the handles. An anti–scissoring mechanism (94) maintains the alignment of the jaws. Within the cartridge ultimate (112), the penultimate (114) clips are moved along a clip path by an active pusher (98), and a passive gate structure (147). As the pusher moves the ultimate clip to its operative position, a spacer (141) of variable length moves the penultimate clip into the gate structure.

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MODULAR LIGATING APPARATUS AND METHOD

Background of the Invention

Field of the Invention

This invention relates generally to ligating clip appliers and, more specifically, to appliers including reusable handle assemblies and disposable multi-clip cartridges.

Discussion of Related Art

Surgical clip appliers commonly include handles operable by a user to close jaws containing a ligating clip. The clips are mounted in the jaws in an open state, and closed around a body conduit to achieve ligation.

Clip appliers of the past have included devices that are totally reusable after sterilization, typically in an autoclave. Such appliers, which have been particularly appreciated for their tactile feedback and "feel", have required the manual loading of the jaws with a single clip. With only a single-clip capability, at least two clip appliers have been required in the surgical environment, along with a surgical assistant who loads the appliers and shuttles them to the surgeon.

These reusable clip appliers have suffered greatly from jaw misalignment, which tends to occur with repeated use. When the jaws are misaligned, the associated clips do not adequately close. In severe cases of misalignment, the clips tend to fall from the jaws before they are applied to the body conduit.

Other clip appliers have included handle assemblies and removable cartridges containing multiple clips in a clip train. These devices have tended to be very complex as a single movement of the handle has been required to move the ultimate clip to an operable location, and to move the penultimate clip to a staging location. To accomplish these objectives, multiple hinges and linkage elements have been required which unfortunately have degraded the tactile feedback associated with the clip closure. This tactile feedback has been further degraded by a camming action which has been used to translate longitudinal movement to lateral movement associated with jaw closure.

Clearly absent from the prior art is a simplified structure, including a reusable handle assembly and disposable clip cartridge suitable for maintaining jaw alignment and tactile feedback.

Summary of the Invention

In accordance with the present invention, a surgical clip applier is provided with a reusable, autoclavable handle assembly which preserves the "feel" particularly appreciated by the surgeons. A disposable clip cartridge, including a train of multiple clips, is removably attached to the handle assembly and operable by the handle assembly to individually attach the clips to a body conduit. Movement of the clip train is limited to a pusher, a spacer, and associated linkage to provide for a simple and direct movement of the clip train. Jaws are preferably formed as part of the disposable cartridge so that new jaws are provided with each cartridge. An interleaved structure of minimum thickness facilitates jaw alignment. The handle assembly includes arms that move laterally to produce a lateral motion in the clip jaws. The direct association between the handle assembly and the jaws provides the tactile feedback heretofore only available with single-clip appliers.

In one aspect of the invention, a clip applier is adapted for use in positioning and actuating a surgical clip relative to body tissue. The applier includes a pair of handles operable by a user and a cartridge containing a plurality of the clips. An attachment mechanism removably attaches the cartridge to the handles. A pair of jaws carried by the cartridge is adapted to receive one of the clips and to be moved by operation of the handles to apply the clip to the body tissue.

In another aspect of the invention, a surgical instrument includes a pair of handles pivotal relative to each other and a pair of jaws each movable by an associated one of the handles along a path of closure between a relatively closed position and a relatively open position. The jaws have a tendency to become misaligned. Portions of one of the jaws define a slot extending along the path of closure. A tab fixed to the other jaw is moveable within the slot to maintain the jaws in alignment.

In an additional aspect, a clip applier having a distal end and a proximal end includes a first clip and a second clip forming a clip train moveable along a clip train path. A pusher has a first pusher position proximal to the first clip and distal of the second clip, and a second pusher

position proximal of both the first clip and the second clip. A gate has a first gate position along the clip train path, and a second gate position removed from the clip train path. A handle assembly is operable toward a first handle position to place the pusher in the first pusher position and to place the gate in the first gate position. The handle assembly is also operable toward a second handle position to place the pusher in the second pusher position and to place the gate in the second gate position.

Still another aspect of the present invention includes a clip applier having an elongate configuration and extending between a proximal end and a distal end. A pair of handles is movable by a user between an open position and a closed position. A cartridge assembly is removably attached to the handles and operable by movement of the handles. A cartridge included in the cartridge assembly individually issues a plurality of clips into a pair of jaws, which can be included in either the handles or the cartridge assembly. The jaws are sized and configured to receive the clips from the cartridge and to change the shape of the clip by movement of the handles. A linkage carried by either the handles or the cartridge assembly is responsive to lateral movement of the handles to produce longitudinal movement of the clips within the cartridge.

Another aspect of the invention includes a ligating clip assembly with an autoclavable handle assembly and a disposable, non-autoclavable clip assembly configured for removable attachment to the handle assembly. A clip cartridge included in the clip assembly removably stores at least one clip. A pair of jaws attached to one of the handle assembly and the clip assembly are adapted to receive the clip from the cartridge. An actuating mechanism included in the handle assembly or the clip assembly is operable to advance the clip into the jaws and to operate the jaws to position the clip relative to an object.

A method for operating a ligating clip assembly comprises another aspect of the present invention. This method includes steps for providing a handle assembly with a pair of handles, and a clip assembly with at least one clip stored in a clip cartridge. A pair of jaws are included in one of the handle assembly and the clip assembly and are configured to receive the clip. An actuating mechanism is also included in the handle assembly or the clip assembly for operating the jaws to close the clip relative to an object. The method includes the steps of autoclaving the handle assembly and disposing of the clip assembly.

In a further aspect of the invention, a ligating clip cartridge assembly is adapted to be removably mounted on a handle assembly. The clip cartridge assembly includes a plurality of clips disposed in a clip train having an ultimate clip and a penultimate clip. A tray having a proximal end and a distal end supports the clip train and includes an operative clip position and a gated clip position. A pusher has properties for moving the ultimate clip distally from the gated clip position to the operative clip position, and a spacer has properties for moving the penultimate clip distally to the gated position.

A method for advancing a clip train, including an ultimate clip and a penultimate clip, into an operative position provides a further aspect of the invention. This method includes the steps of providing a tray to support the clips along a clip train path extending between a distal end and a proximal end of the tray. The tray has a gated position along the clip train path. The ultimate clip is pushed to the operative position, and during this pushing step, a spacer of variable length moves the clip train distally until the penultimate clip arrives at the gated position of the tray.

Brief Description of the Drawings

Fig. 1 is a side-elevation view of a patient with a vascular side branch and a clip applier of the present invention operable to occlude the side branch;

Fig. 2 is a perspective view of one embodiment of the clip applier;

Fig. 3 is a top-plan view of the embodiment of Figure 2;

Fig. 4 is an expanded view of the embodiment of Figure 2 showing a handle assembly and removable cartridge assembly;

Fig. 5 is a top-plan view of the cartridge assembly illustrated in Figure 4;

Fig. 6 is an expanded view of the cartridge assembly illustrated in Figure 4;

Fig. 7 is a top-plan view of the cartridge assembly illustrating direct operation of cartridge jaws by the handle assembly;

Fig. 8 is a perspective view of the interior regions of the cartridge assembly illustrating a first step in a preferred method of operation;

Fig. 9 is a side-elevation view partially in section taken along lines 9-9 of Figure 8;

Fig. 10 is a perspective view illustrating another step in a preferred method of operation;

Fig. 11 is a cross-section view taken along lines 11-11 of Figure 10;

Fig. 12 is a perspective view illustrating an additional step in a preferred method of operation;

Fig. 13 is a cross-section view taken along lines 13-13 of Figure 12;

Fig. 14 is a perspective view illustrating a further step in a preferred method of operation;

Fig. 15 is a cross-section view taken along lines 15-15 of Figure 14;

Fig. 16 is a perspective view of a further embodiment of the clip applier;

Fig. 17 is an expanded view of the clip applier of Figure 16 illustrating a handle assembly and removable cartridge assembly;

Fig. 18 is an expanded view of the cartridge assembly illustrated in Figure 17;

Fig. 19 is a perspective view of portions of the cartridge assembly illustrating a jaw assembly in a step associated with a preferred method of operation;

Fig. 20 is a perspective view of interior portions of the cartridge assembly further illustrating the method step of Figure 19;

Fig. 21 is a perspective view of the interior portions of the cartridge illustrating the jaw assembly in another step of the preferred method of operation;

Fig. 22 is a perspective view of the interior portions of the cartridge further illustrating the method step of Figure 21;

Fig. 23 is a perspective view of the interior portions of the cartridge assembly illustrating the jaw assembly in an additional step of a preferred method of operation;

Fig. 24 is a perspective view of the interior portions of the cartridge further illustrating the method step of Figure 23;

Fig. 25 is a perspective view of the interior portions of the cartridge illustrating the jaw assembly in a further step of the preferred method of operation;

Fig. 26 is a perspective view of the interior portions of the cartridge further illustrating the method step of Figure 25;

Fig. 27 is a perspective view of a further embodiment of the jaw assembly having floating characteristics, the view showing the jaw assembly in a fully-closed configuration;

Fig. 28 is a perspective view similar to Fig. 29 and showing the floating jaws in a fully-opened configuration; and

Fig. 29 is a perspective view of the jaw assembly illustrating an initial step of closure beginning at the distal tip of the jaws.

Detailed Description of the Preferred Embodiments and Best Mode of the Invention

A clip applier is illustrated in Figure 1 and designated generally by the reference numeral 10. The clip applier 10 is a surgical instrument particularly adapted for use in closing or occluding blood vessels and other body conduits of a patient 12. The blood vessels may be relatively large, as in the case of the femoral artery 14, or may be relatively small, as in the case of side branches 16 of the saphenous vein 18. In each case, it is the purpose of the clip applier 10 to percutaneously engage the particular body conduit, such as the side branch 16, to position a clip along the conduit, and to crimp the clip in a closed state to occlude the conduit. The need for this type of vessel occlusion is particularly apparent in a procedure where the saphenous vein 18 is harvested to facilitate by-pass surgery. In this procedure, the side branches 16 are severed from the saphenous vein 18 and must be occluded to prevent bleeding.

One preferred embodiment of the clip applier 10 is illustrated in the perspective view of Figure 2. In this view, it can be seen that the clip applier 10 will typically include a handle assembly 21 and a removable clip cartridge assembly 23. These two assemblies 21 and 23 are joined by linkage 25 so that operation of the handle assembly 21 also operates the cartridge assembly 23 in order to issue and crimp a clip as previously discussed. The handle assembly 21 will typically have a scissors configuration with a pair of legs 27 and 30 and a pair of arms 32 and 34 separated by a pivot point or fulcrum 36. In a common manner, the leg 27 and arm 34 form one piece of the handle assembly 21 while the leg 30 and arm 32 form a second piece of the handle assembly 21. These two pieces are joined by a fulcrum pin at the fulcrum 36, so that they pivot relative to each other about an axis 38.

Finger-and-thumb holders 47 and 50 are provided at the proximal end of the legs 27 and 30. At the distal end of the arms 32 and 34, a pair of projections 52 and 54 extend downwardly toward the cartridge assembly 23. These projections 52 and 54 extend into the page in the top-plan view of Figure 3.

A bottom perspective view of the clip applier 10 is illustrated in Figure 4, with the handle assembly 21 separated from the cartridge assembly 23. Mounting the cartridge assembly 23 to the handle assembly 21 is facilitated by providing the bottom of the fulcrum pin 36 with an annular flange 56. This flange 56 is mateable with an opening 58 in the top of the cartridge

assembly 23, as best illustrated in Figure 5. This opening 58 has an enlarged end suitable to receive the full diameter of the annular flange 56 and a smaller end for engaging and holding the annular flange 56 in the opening 58. The fulcrum pin 36 and associated annular flange 58 are suitably retained in the opening 58, to provide the cartridge assembly 23 with a removable, but generally fixed, relationship with the fulcrum pin 36. It will be noted that when the cartridge assembly 23 is fixed to the fulcrum pin 36, each of the legs 27, 30 and the arms 32, 34 is free to move relative to the cartridge assembly 23.

With further reference to Figures 4 and 5, it will be noted that the cartridge assembly 23 includes a clip tray 65 and a pair of covers 67 and 70 which form a housing 72. At the distal end of the housing 72, and a pair of jaws 74 and 76 are configured to receive a clip 78. These jaws 74 and 76 are accessible by the projections 52 and 54, respectively, of the handle assembly 21 through windows 81 and 83 in the cover 67. Importantly, operation of the handle assembly 21 causes the projections 52 and 54 to directly engage the jaws 74 and 76 without intervening parts or linkage, thereby providing a high degree of tactile feedback to the surgeon as the clip 78 is applied. In particular, it will be noted that the jaws 74 and 76 close by moving in a lateral direction. This is the same direction that the projections 52 and 54 move as they engage the jaws 74, 76 and move the jaws 74, 76 to close the clip 78. As a result, substantially all of the lateral force directed to clip closure is communicated directly to the handle assembly 21.

Figure 4 also provides a bottom-perspective view of the linkage 25, which in this embodiment includes a pair of levers 85 and 87 which engage the legs 27 and 30 through living hinges 90 and 92, respectively. The levers 85 and 87 are also joined through a living hinge 94 to a central member 96. This central member 96 is operably coupled to a pusher 98 in the cartridge assembly 23 in a manner discussed in greater detail below. With this construction, it can be seen that movement of the legs 27 and 30 of the handle assembly 21 causes the central member 96 to move the pusher 98 back and forth along an axis 101. More specifically, when the legs 27 and 30 are moved toward each other in the direction of arrows 103 and 105, the central member 96 and pusher 98 are drawn proximally along an arrow 107. Conversely, when the legs 27 and 30 are opened or separated, the member 96 and associated pusher 98 are moved distally.

An exploded view of the cartridge assembly 23 is illustrated in Figure 6 where the tray 65, jaws 74 and 76, pusher 98, and covers 67 and 70 are separated to illustrate their detail.

Also illustrated in this view is a train 110 of the clips 78 which are movable along the tray 65 and include an ultimate clip 112 and a penultimate clip 114.

From this view it can also be seen that the cover 70 is associated with a jaw support 116 having a pair of posts 118 and 121 which are adapted to receive the jaw 74, and a pair of posts 123 and 125 which are adapted to receive the jaw 76. An anti-scissoring mechanism 126 includes a flange 127 formed on the jaw 74 and an associated slot 130 provided on the jaw 76. This flange 127 mates with the slot 130 in order to maintain the jaws 74 and 76 in alignment.

The pusher 98 has an elongate configuration with the pair of flanges 132 at its distal end, which extend downwardly in Figure 6. These flanges 132 form ramps 134 which incline upwardly and proximally of the pusher 98. A plurality of openings are formed along the length of the pusher 98 and include a proximal opening 136 and an adjacent distal opening 138.

A spacer 141 is provided to move the clip train 110 along the tray 65. The length of the spacer 141 is variable between its distal end and its proximal end, and includes a projection 143 with a ramp 145 that extends upwardly and distally in Figure 6. It is the projection 143 of the spacer 141 which is adapted to be progressively received within the openings, such as the openings 136 and 138, of the pusher 98.

Of further interest in Figure 6 is a gate 147 which is provided in the distal bottom of the tray 65. This gate 147 includes a slot 152 and is pivotal on a living hinge 154 between an upper position and a lower position. In the upper position, the gate 147 extends into the path of the clip train 110. In the lower position, the gate 147 is removed from the path of the clip train 110.

The jaws 74 and 76 can be mounted on the jaw support 116 and relative to the posts 118-125 in the manner illustrated in Figure 7. This top view is of particular interest as it illustrates the relationship between the projections 52 and 54 of the handle assembly 21 and the associated jaws 74 and 76 of the cartridge assembly 23. These projections 52 and 54 extend through the windows 81 and 83, respectively, to engage the jaws 74 and 76. It is important to note that there is direct contact between the projections 52 and 54 and the associated jaws 74 and 76 without any intervening linkage, levers or camming action. This direct contact provides a significant advantage to the present invention in the form of tactile feedback which is communicated directly from the jaws to the user. This greatly facilitates the "feel" which is much appreciated by a surgeon using the clip applier 10.

Operation of the clip applier is best discussed with reference to the progressive steps illustrated in Figures 8-12. In these views, the jaw 74 is illustrated, but its support 116 is not shown in order to expose the interior of the clip tray 65. These views are particularly beneficial in showing operation of the pusher 98 relative to the clip train 110, the gate 147, and spacer 141.

An initial position of the pusher 98 is illustrated in the perspective view of Figure 8 and the cross-section view of Figure 9. In this initial position, the distal end of the pusher 98, which includes the flanges 132, is disposed between the ultimate clip 112 and the penultimate clip 114. In this position, the flanges 132 of the pusher 98 pivot the gate 147 downwardly about its living hinge 154, as best illustrated in Figure 9. In this downward position, the gate 147 is removed from the path of the clip train 110. With the flanges 132 disposed in the path of the clip train 110, any distal movement of the clips by the spacer 141 is inhibited.

As the pusher 98 is moved distally by operation of the handle assembly 21 and linkage 25, the ultimate clip 112 is pushed by the flanges 132 distally into the jaws 74 and 76. This is best illustrated in the perspective view of Figure 10 and associated cross-sectional view of Figure 11. As the flanges 132 of the pusher 98 are moved distally, the clip train 110 is freed so that it can be moved distally by the spacer 141.

In Figure 10, the spacer 141 is illustrated to have a distal end 156 and a proximal end 158 interconnected by a pair of legs 61 and 63 which are variable in length. These legs 161 and 163 are biased to an elongate configuration, but compressible to exert a distal force on the clip train 110. The projection 143 of the spacer 141 is disposed at the proximal end 158 and adapted to be received in one of the openings, such as the opening 138, in the pusher 98. As the pusher 98 is moved distally, the proximal end 158 of the spacer 141 is also moved distally. This tends to compress the legs 161, 163, thereby exerting the distal force on the clip train 110.

It will be apparent that movement of the pusher 98 distally causes the flanges 132 to clear the gate 147 so that it is free to pivot upwardly into the path of the clip train 110. However, this upward movement of the gate 147 will be opposed by the penultimate clip 114 until it feeds in the slot 152 of the gate 147.

Further movement of the pusher 98 in the distal direction moves the ultimate clip 112 into its operative position at the distal end of the jaws 174 and 176. This position is best illustrated in the perspective view of Figure 12 and the associated cross-sectional view of Figure 13.

With the pusher 98 in its distal-most position, the legs 161, 163 of the spacer 141 may be fully compressed, as illustrated in Figure 12. This will create a maximum distal force on the clip train 110 operating to move the penultimate clip 114 into the slot 152, and enabling the gate 147 to rise fully into its upper-most position in the path of the clip train 110. In this position, the forward edge of the slot 152 engages the penultimate clip 114 where it is held in its gated position at the distal end of the tray 65. With the penultimate clip 114 held by the gate 147, any further movement of the clip train 110 in the distal direction is inhibited.

With the ultimate clip 112 loaded into its operative position in the jaws 74, 76, the pusher 98 can be withdrawn by operation of the handle assembly 21 and associated linkage 25. This proximal movement of the pusher 98 is caused by moving the legs 27 and 30 of the handle assembly 21 toward each other. This movement also causes the projections 52 and 54 of the associated arms 32 and 34 to directly move the jaws 74 and 76 toward each other, thereby crimping the clip 112 onto the conduit, such as the side branch 16 (Figure 1).

During this closure of the handle assembly 21, the pusher 98 is withdrawn in the proximal direction where it engages the clip train 110 as the ramps 134 of the flanges 132 cam over the penultimate clip 114. This is best illustrated in the perspective view of Figure 14 and associated cross-sectional view of Figure 15. This use of the clip 114 in a camming action is desirable as both the pusher 98 and the clip 114 are preferably made of metal. These materials are better suited for the high pressure sliding movement of a camming action, than a plastic material such as that preferably forming the tray 65.

Figure 14 also illustrates operation of the spacer 141 as the pusher 98 is withdrawn. In particular, it will be noted that the spacer 149 can be provided with a pair of ears 165 and 167, which progressively register with distally-facing slots 170 and 172 in the sides of the tray 65. As the distal end 156 of the spacer 141 moves distally, the ears 165, 167 progressively engage a different pair of the slots 170, 172 (best shown in Figure 8). This engagement prevents the spacer 141 from moving proximally as the pusher 98 is withdrawn. With the spacer 141 held stationary, proximal movement of the pusher 98 causes the projection 143 to withdraw from the proximal opening 136 along the ramp 145. This projection 143 slides along the pusher 98 until it snaps into the next opening, in this case the distal opening 138.

Upon further withdrawal of the pusher 98, the flanges 132 at the distal end of the pusher 98 clear the penultimate clip 114 and fall into the path of the clip train 110 again

depressing the gate 147 as initially illustrated in Figures 8 and 9. From this point, the legs 27 and 30 of the handle assembly 21 can again be expanded to move the pusher 98 forward and load the penultimate clip 114 into the jaws 74 and 76.

A further embodiment of the invention is illustrated in Figure 16 where elements of similar structure are designated by the same reference numerals, followed by the lower-case letter "a". By way of example, this embodiment includes a clip applier 10a with a handle assembly 21a, a cartridge assembly 23a, and associated linkage 25a. The handle assembly 21a includes finger holders 47a and 50a attached to legs 27a and 30a at the proximal end, and projections 52a and 54a attached to arms 32a and 34a, respectively, at the distal end. The cartridge assembly 23a includes a clip tray 65a and a cover 67a, which form a housing 72a. Jaws 74a and 76a extend downwardly at the distal end of the cartridge assembly 23a, in a direction opposite to that of the projections 52a and 54a.

As best illustrated in Figure 17, the cartridge assembly 23a in this embodiment is attached to the handle assembly 21a by a projection 181, which can be snap-fit into a cylindrical hole 183 formed in the fulcrum 36a. Attachment of the linkage 25a to the handles 27a and 30a is facilitated by detent assemblies 185 and 187, respectively.

The expanded view of Figure 18 shows various other elements which are similar to those described in the embodiment of Figure 6. These elements include the jaws 74a and 76a, which in this embodiment are formed as part of a jaw assembly 190. This assembly 190 includes not only the anti-scissoring mechanism 126a, but also a pair of arms 192 and 194 which extend into an associated pair of legs 196 and 198. The arms 192, 194 are separated from the legs 196, 198 by a pivot hole 201, which is adapted to mount on a pivot post 203 associated with the jaw support 116a. In a manner disclosed in greater detail below, the arms 192, 194 have a scissoring relationship, while the legs 196 and 198 have an interfering relationship which tends to bias the jaw assembly 190 toward an open position.

Figure 18 is perhaps the best view to discuss another feature of this embodiment which is associated with the anti-scissoring mechanism 126a. This mechanism is similar to that previously discussed except that the surfaces forming the slot 130 in the Figure 6 embodiment are formed by two separate fingers 193 and 195 associated with the jaws 74a and 76a, respectively. The flange 127 of the Figure 6 embodiment is also separated into a pair of fingers 197 and 199 associated with the jaws 74a and 76a, respectively. These finger pairs 193,

195 and 197, 199 are interleaved in order to prevent any scissoring of the arms 192 and 194 and associated jaws 74a and 76a. Thus, the finger 193 is disposed beneath the finger 199, thereby preventing any upward movement of the jaw 74a relative to the jaw 76a. Similarly, the finger 197 is disposed over the finger 195 to prevent any downward movement of the jaw 74a relative to the jaw 76a.

The pusher 98a is similar to that previously discussed with the flanges 132a at the distal end. A pin 205 extends downwardly from the pusher 98a in the same direction as the flanges 132a, but at the proximal end of the pusher 98a. A tab 206 is also provided at the proximal end of the pusher 98 to receive one end of a tension spring 207, the other end of which is fixed to the cover 76a. The spring 207 tends to bias the pusher 198 in the distal direction. The pusher 98a can also be provided with a pair of leaf springs 210, which are biased outwardly to engage ratchets and cams on the lateral surfaces of the cover 76a. This structure insures completion of a full clip cycle before initiating a subsequent cycle. This is accomplished by moving the leaf springs 210 along a ratchet in the proximal direction and then along a cam in the proximal direction.

This embodiment also includes the clip train 110a with an ultimate clip 112a and penultimate clip 114a. This clip train 110a is moved in a distal direction by the spacer 141a, which in this embodiment has but a single leg 163a of variable length. As in the previous embodiment, the projection 143a is provided at the proximal end of the spacer 141a. The clip train 110a and associated spacer 141a move along a clip train path 212 in the tray 65a. The gate 147a can be provided at the distal end of this path 212 in the manner previously described.

The spacer 141a in this embodiment includes a distal U-shape member 211, but differs in several respects from the spacer 141 previously described. For example, the ears 165 and 167 of the spacer 98 which register with the slots 170 and 172 of the tray 65, respectively, are replaced by a single tooth 215 on the bottom side of the member 211, which register progressively with slots, such as the slots 217 and 219, in the tray 65a. The tooth 215 and associated slots, such as the slots 217 and 219, function as a ratchet mechanism 220 to permit distal movement of the member 211 while inhibiting rearward movement of the member 211.

The linkage 25a of this embodiment include the detent assemblies 185 and 187, which respectively engage the handles 27a and 30a, as previously disclosed. These assemblies 185 and 187 are each attached to an associated lever arm 214 and 216, thus the detent assembly 185

pivots with the arm 214 about a fulcrum 218. Similarly, the detent assembly 187 pivots with the arm 216 about a fulcrum 221. Each of the detent assemblies 185 and 187 includes a cupped flange 123 and 125, and a support 127 and 130, respectively, which engage the associated leg 27a and 30a of the handle assembly 21a. The flange supports 227 and 230 are relatively long, to facilitate mounting the flanges 223 and 225, but are bent back on themselves to provide a short moment arm relative to the associated fulcrums 218 and 221, respectively. Operation of the resulting linkage 25a produces a progressive scissoring action of the lever arms 214 and 216 as the associated legs 27a and 30a of the handle assembly 21a are moved relative to each other. This operation of the linkage 25a will be better understood with a description of the progressive steps of operation and reference to the associated drawings of Figures 19-26.

Figure 19 is a perspective view of the cartridge assembly 23a with the cover 67a removed to expose the jaw assembly 190. This view illustrates a moment in time when the ultimate clip 112a is about to be loaded into the jaws 74a and 76a. The handle assembly 21a has been closed bringing the legs 27a and 30a into close proximity, along with the attached detent assemblies 185 and 187 associated with the linkage 25. This close proximity has caused the arms 214 and 216 to scissor forming a variable V-groove 240 which moves along a slot 241 at the proximal end of the tray 65a. The pin 240 at the proximal end of the pusher 98a seats in this V-groove and slot 241, and is carried proximally with the pusher 98a, as illustrated in Figure 19. This movement of the pusher 98a relative to the cover 76a expands the spring 207 thereby biasing the pusher 98a in a distal direction. Upon release of the leaf springs 210 from the associated ratchet, in the manner previously discussed, the pusher 98a is free to move under the bias of the spring 207 pushing the ultimate clip 212a into the slots of the jaws 74a and 76a.

The same step of operation is illustrated in Figure 19 and in Figure 20 where the jaw assembly 190 has been removed to expose the pusher 98a and clip train 110a. Note that the presence of the projection 143a of the spacer 141a in the distal hole 136 of the pusher 98a begins compression of the spacer 141a which biases the clip train 110a in the distal direction.

Figures 21 and 22 illustrate a step of operation where the ultimate clip 112a is moved to its operative position within the jaws 74a and 76a. Figure 21 illustrates the jaw assembly 190 with the jaws 74a and 76a fully separated to receive the clip 112a. In this state, the interfering relationship between the legs 196 and 198 is relieved with the jaws 74a and 76a maximally separated.

The next step in the method of operation is illustrated in Figures 23 and 24. After the ultimate clip 112a has been loaded in its operative position in the jaws 74a and 76a, the handle assembly 21a can be moved to a closed position bringing the legs 27a and 30a into closer proximity. In the manner previously discussed, this causes the arms 32a and 34a of the handle assembly 21a to also move into proximity, directly pressing the projections 52a and 54a (Figure 16) against the respective jaws 74a and 76a. In this manner, operation of the handle assembly 21a begins to close the jaws 74a, 76a, clipping the clip 112a. With reference to Figure 23, it will be noted that the legs 196 and 198 associated with jaw assembly 190 are forced against each other as the jaws 74a and 76a are closed. The interfering fit, which prevents any scissoring action of the legs 196 and 198, causes these legs to bend slightly, thereby biasing the jaws 74a and 76a to the open position. Further closure of these jaws increases the bending and, therefore, the bias associated with the interfering legs 196 and 198.

Referring now to Figure 24, it will be noted that closure of the handle assembly 21a also moves the detent assemblies 185 and 187 into closer proximity. This causes the assemblies 185 and 187 to pivot slightly on the associated fulcrums 218 and 221, thereby causing the associated lever arms 214 and 216 to move the V-groove proximally along the slot 241. The pin 205 is carried in this V-groove proximally along the slot 241 drawing with it the remainder of the pusher 98a. This withdraws the flanges 132a over the penultimate clip 114a, spreads the spring 207, and begins movement of the leaf springs 210 along the associated ratchet.

In the previous step, illustrated in Figure 22, the projection 143a associated with the spacer 141a was seated in the proximal hole 136a of the pusher 98a. As the pusher 98a is drawn proximally, in the step illustrated in Figure 23, it tends to draw the projection 143a and hence the spacer 141a in the proximal direction. However, this tendency has different effects at the different ends of the spacer 141a. At the proximal end, the projection 143a will move with the hole 136a a short distance as the leg 163a expands to its normal state. At the distal end of the spacer 141a, the U-shape member 211 cannot move proximally due to the action of the ratchet 213. With the U-shape member 211 held stationary, and the projection 143a moving proximally, the leg 163a expands, and the spacer 141a elongates. This occurs until the leg 163a is pulled beyond its natural state, at which point the projection 143a is withdrawn from the hole 136a. Further proximal movement of the spacer 98a causes this projection 143a to snap into the distal hole 138a.

The next step in the operative process is illustrated in Figure 25 and 26 where the ultimate clip 212 is fully compressed. This occurs primarily by operation of the handle assembly 121a where the legs 27a and 30a (Figure 16) are fully closed. By direct contact between the arms 32a and 34a (Figure 16) and the jaw assembly 190, the jaws 74a and 76a are also fully closed to crimp the clip 112a. With the jaws 74a and 76a fully closed, the legs 196 and 198 associated with the jaws assembly 190 are fully strained to maximize the bias tending the open the jaws 74a and 76a.

With reference to Figure 26, it can be seen that the full closure of the handle assembly 121a (Figure 16) operates to move the detent mechanisms 185 and 187 into their most proximal relationship. This causes the lever arms 214 and 216 to rotate proximally so that the V-groove 240 carries the projection 205 toward the proximal end of the slot 241. This draws the pusher 98a to its most proximal position moving the spring 207 to its fully expanded state.

Another embodiment of the jaw assembly is illustrated in Figures 27-29 where elements of structure similar to those previously discussed are designated by the same reference numerals, followed by the lower-case letter "b". For example, in Figure 27, the jaw assembly 190b includes the jaws 74b and 76b and associated legs 196b and 198b, with the anti-scissoring mechanism 126b disposed there between. As in the previous embodiment, this jaw assembly 190b can be mounted on the jaw support 116b, but in this case, only a single post 250 is required. The arms 32b and 34b and associated projections 52b and 54b, of the handle assembly 21b, are also illustrated in Figure 27.

This jaw assembly 190b differs from those previously discussed, as it includes a floating hinge structure 252 disposed at the proximal end of the assembly 190b. This floating hinge structure 252, in the illustrated embodiment, includes a pair of slots 254 and 256 which extend laterally at the proximal end of the respective legs 196b and 198b. The single post 250 extends into each of the slots 254 and 256, but has a width which is less than the lateral extension of the slots 254 and 256. As a result, the proximal end of the legs 196b and 198b are free to move laterally or float from a first position wherein the post 250 engages the inner ends of the slots 254, 256, to a second position wherein the post 250 engages the outer ends of the slots 254, 256. A leaf spring 258 can be provided to bias the legs 196b and 198b to the first position where they are maximally separated and the post 250 engages the inner ends of the slots 254, 256 as illustrated in Figure 27.

This structure of the jaw assembly 190b is of particular advantage as it permits closure of the jaws 174b, 176b in a method which insures that the associated clip 78b is closed first at its distal end. This closure process begins when the projections 52b and 54b of the arms 32b and 34b are moved laterally against the jaws 74b and 76b, respectively. This step in the closure process is best illustrated in Figure 28 where the distal tip of the jaws 74b and 76b are moved together, while the spring 258 maintains the floating hinge 252 in its first expanded position. With the legs 196b and 198b maintained in an expanded, generally-spaced relationship, and the tips of the jaws 74b and 76b brought into proximity, the distal end of the clip 78b is generally closed, while the proximal end of the clip 78b is maintained generally open.

With the tips of the jaws 74b and 76b closed, they provide a pivot point which causes the further pressure of the projections 52b and 54b on the jaws to close the proximal end of the legs 196b and 198b. This closure is accommodated by the floating hinge 252, which moves to its second, contracted configuration, as best illustrated in Figure 29. With the distal end of the jaws 74b and 76b closed, this closure of the proximal ends causes the proximal end of the clip 78b to be closed, thereby forming the clip 78b into its fully-closed configuration. This preferred method of operation is facilitated in a preferred embodiment wherein the post 250 has a diameter of .060 inches, and the slots 254 and 256 each have an axial width of .060 inches and a lateral length of .140 inches. It will be apparent that this embodiment, including the single post 250 and two slots 254 and 256, could be replaced by multiple posts each associated with one of the legs 196b and 198b and movable within individual slots or the same slot in the jaw support 116b.

Having discussed the preferred embodiments of the concept and their methods of operation, it is apparent that the clip applier 10a provides significant advantages over previous structures. The surgeons will particularly appreciate the "feel" associated with the device. This "feel" is enhanced by the non-disposable scissor assembly 21 which provides a weight and structure familiar to the surgeon. The disposable clip assembly 23 is easily mounted on this structure to provide for multiple clip applications. The "feel" is further enhanced by the direct pressure of the scissor assembly 21 on the jaws 74 and 76. The mechanism of the cartridge assembly 23 is of ultimate simplicity and comprised primarily of only two operative members, namely the pusher 98 and the spacer 141. Of these two elements, only the pusher 98 is actively involved as the spacer 141 is provided with two ratcheting components which cause it to move

forwardly by operation of the pusher 98. This forward movement is enhanced by the expandable leg 163 so that the spacer 141 tends to function passively and with a motion similar to that of an inchworm.

The active motion of the pusher 98 is facilitated by the distal bias of the compression spring 207. Proximal movement of the pusher 98 is accomplished by the movement of the V-groove 240, defined by the arms 214 and 216, along the slot 241.

Although the foregoing embodiments and methods of operation have been described in significant detail, it will be apparent that this invention is a concept which may be otherwise embodied. As a result, one is cautioned not to determine the nature of the concept solely with reference to the described embodiments and method steps, but rather with particular reference to the following claims.

CLAIMS

1. A clip applier for applying a clip to an object, the clip applier comprising:

the handle assembly having a pair of opposing legs and a pair of opposing arms, the legs being operable to move the arms pivotally about a fulcrum;

a clip cartridge adapted to be mounted on the handle assembly and to issue one of a plurality of clips;

a pair of jaws included in one of the handle assembly and the clip cartridge, the jaws being configured to receive the one clip from the clip cartridge; and

the arms of the handle assembly being positioned to directly engage the jaws without intervening linkage, to close the jaws by operation of the legs of the handle assembly, to apply the one clip to the object.

2. The clip applier recited in Claim 1 wherein the clip cartridge is mounted to the handle assembly at the fulcrum.

3. The clip applier recited in Claim 1 wherein the clip cartridge is mounted to the handle assembly in a pivotal relationship with each of the legs and the arms of the handle assembly.

4. The clip applier recited in Claim 3 wherein the clip cartridge is mounted to the handle assembly and has a length which extends generally between the opposing legs of the handle assembly and the opposing arms of the handle assembly.

5. The clip applier recited in Claim 1 wherein:

the handle assembly includes a fulcrum pin disposed at the fulcrum; and

the cartridge is connected to the fulcrum pin of the handle assembly.

6. The clip applier recited in Claim 1 wherein:

the jaws move in a lateral direction to close the clip; and

the arms of the jaw assembly move substantially in the lateral direction to engage

the jaws and to close the jaws on the clip.

7. The surgical clip jaw assembly, comprising:

a supporting structure;

a jaw assembly mounted on the supporting structure and having a proximal end and a distal end;

a jaw assembly having a proximal end and a distal end, with a pair of opposing jaws each having a distal tip at the distal end of the jaw assembly; and

a floating hinge structure disposed at the proximal end of the jaw assembly and having an expanded state facilitating closure of the distal tip of the jaws and a contracted state facilitating full closure of the jaw assembly.

8. The surgical clip jaw assembly recited in Claim 7, further comprising a spring disposed between the opposing jaws for biasing the floating hinge structure to the expanded state.

9. The surgical clip jaw assembly recited in Claim 8 wherein the spring has a U-shape configuration and a pair of opposing ends, each coupled to an associated one of the jaws of the jaw assembly.

10. A surgical clip cartridge adapted to be inserted on a pair handles, and being openable by the handles to position a surgical clip relative to body tissue, comprising:

a cartridge containing a plurality of the clips;

an attachment mechanism for removably attaching the cartridge to the handles; and

a pair of jaws carried by the cartridge and being adapted to receive one of the clips from the cartridge, the jaws being directly movable by operation of the handles to apply the one clip to the body tissue.

11. The cartridge recited in Claim 10 wherein the jaws are attached to the cartridge and form with the cartridge a cartridge assembly removably mountable on the handles.

12. The cartridge recited in Claim 10 wherein the jaws are movable by operation of the handles between a first jaw position, to receive the one clip, and a second jaw position, to apply the one clip to the body tissue.

13. The cartridge recited in Claim 10, further comprising:

a linkage caused by the cartridge and adapted to engage the handles; and

the linkage being responsive to operation of the handles to advance the one clip from the cartridge into the jaws.

14. The cartridge recited in Claim 10, further comprising:

a jaw assembly including a pair of arms disposed relative to the handles and each extending distally to an associated one of the pair of jaws.

15. The cartridge recited in Claim 14, wherein the arms of the jaw assembly include metal, and the jaws of the jaw assembly include plastic.

16. A surgical instrument, comprising:

a pair of handles pivotal relative to each other at a pivot point;

a pair of jaws each movable with an associated one of the handles along a path of closure between a relatively closed position and a relatively open position, the jaws having a tendency to become misaligned;

portions of one of the jaws defining a slot extending along the path of closure; and

a tab fixed to the other of the jaws and movable within the slot to maintain the jaws in alignment along the path of closure.

17. The surgical instrument recited in Claim 16 wherein the slot and the tab have a generally planar configuration.

18. The surgical instrument recited in Claim 16 wherein the surgical instrument is a clip applier and the jaws are sized and configured to receive a ligating clip.

19. The surgical instrument recited in Claim 16, further comprising:

a jaw assembly including a pair of arms associated with the handles; wherein

the portions defining the slot and the tab are included in an associated one of the arms; and

the jaws are attached to an associated one of the slot portions and the tab.

20. The surgical instrument recited in Claim 16, wherein:

the portions defining the slot include first portions defining a first slot and second portions defining a second slot; and

the tab is disposed between the first slot portions and the second slot portions.

21. The surgical instrument recited in Claim 16, wherein:

the slot as defined by a first slot portion having a first surface and a second slot portion having a second surface; and

the tab includes a third surface operable relative to the first surface of the first slot portions, and a fourth surface operable relative to the second surface of the second slot portions.

22. The surgical instrument recited in Claim 21 wherein the first slot portions are longitudinally spaced relative to the second slot portions.

23. The surgical instrument recited in Claim 22 wherein the first surface of the first slot portions and the second surface of the second slot portions are disposed in a common plane.

24. A clip applier having a distal end and a proximal end, comprising:

a first clip;

a second clip forming a clip train with the first clip and movable with the first clip along a clip train path;

a pusher having a first pusher position proximal of the first clip and distal of the second clip, and a second pusher position proximal of the first clip and the second clip;

a gate having a first gate position along the clip train path, and a second gate

position removed from the clip train path; and

a handle assembly including a pair of opposing handles operable toward a first handle position to place the pusher in the first pusher position and to place the gate in the first gate position, and a second handle position to place the pusher in the second pusher position and to place the gate in the second gate position.

25. The clip applier recited in Claim 24 wherein the gate is biased to the first gate position by a living hinge.

26. The clip applier recited in Claim 25, wherein:

the first clip has an initial clip position when the pusher is in the first pusher position;

the gate has portions defining a notch sized and configured to individually receive the clips; and

the first clip in the initial clip position is disposed in the notch of the gate.

27. The clip applier recited in Claim 24 wherein the pusher in the second pusher position forces the gate to the second gate position.

28. The clip applier recited in Claim 24 further comprising a linkage extending between the handles and the pusher, wherein lateral movement of the handles is accompanied by axial movement of the pusher.

29. A clip applier having an elongate configuration and extending between a proximal end and a distal end, comprising:

a pair of handles movable by a user between an open position and a closed position;

a cartridge assembly removably attached to the handles and operable by movement of the handles;

a cartridge included in the cartridge assembly for individually issuing a plurality of clips;

a pair of jaws alternatively included in one of the handles and the cartridge assembly, the jaws being sized and configured to receive the clips issued from the cartridge and to change the shape of the clips by movement of the handles; and

a linkage carried by one of the handles and the cartridge assembly, the linkage being responsive to lateral movement of the handles to produce longitudinal movement of the clips within the cartridge.

30. The clip applier recited in Claim 29 wherein the linkage is formed as part of the cartridge assembly and removably coupled to the handles.

31. The clip applier recited in Claim 29 wherein linkage is formed as part of the handles and removably coupled to the cartridge assembly.

32. The clip applier recited in Claim 29 wherein the cartridge assembly further comprises a clip pusher longitudinally movable within the cartridge to individually issue the clips, the clip pusher being coupled by the linkage to the handles.

33. The clip applier recited in Claim 29 wherein the linkage is attached to the handle and the clip pusher is removably coupled to the linkage.

34. The clip applier recited in Claim 29, wherein:

the jaws include a first jaw and a second jaw opposing the first jaw; and

the first jaw includes portions defining a slot and the second jaw includes a tab movable within the slot to maintain the first jaw in alignment with the second jaw.

35. The clip applier recited in Claim 29, further comprising:

a jaw assembly including an arm attached to an associated one of the handles and an associated one of the jaws; and

the jaw arm of the jaw assembly including metal and the associated jaw of the jaw assembly including plastic.

36. The clip applier recited in Claim 29, wherein:

the handles are movable generally in a plane having a first side and a second side;

the jaws are curved to extend distally in the direction of the first side of the plane; and

the cartridge is removably attached to the handles on the first side of the plane.

37. The clip applier recited in Claim 29 wherein the linkage includes at least one mounting bracket for releasably engaging an associated one of the handles, the bracket being variable in size to accommodate handles of different diameter.

38. The clip applier recited in Claim 37 wherein the mounting bracket includes a living hinge.

39. A surgical clip assembly, including:

a reusable, autoclavable handle assembly;

a disposable, non-autoclavable clip assembly configured for removable attachment to the handle assembly;

a clip cartridge included in the clip assembly for storing at least one clip;

a pair of jaws alternatively attached to one of the handle assembly and the clip assembly, the jaws being adapted to receive the clip from the cartridge; and

an actuating mechanism included in one of the handle assembly and the clip assembly, the actuating mechanism being operable to advance the clip into the jaws.

40. The surgical clip assembly recited in Claim 39 wherein the jaws are attached to the handle assembly.

41. The surgical clip assembly recited in Claim 39 wherein the jaws are attached to the clip assembly.

42. The surgical clip assembly recited in Claim 39 wherein the actuating mechanism is removably attached to the handle assembly.

43. The surgical clip assembly recited in Claim 39 wherein the actuating mechanism is removably attached to the clip assembly.

44. The surgical clip assembly recited in Claim 39 wherein the jaws are reusable and autoclarable.

45. The surgical clip assembly recited in Claim 39 wherein the jaws are integral with the handle assembly.

46. The surgical clip assembly recited in Claim 39 wherein the actuating mechanism includes at least one living hinge.

47. The surgical clip assembly recited in Claim 39 wherein the jaws are removably attached to the handle assembly.

48. A method for operating a ligating clip assembly, comprising the steps of:

providing a handle assembly including a pair of handles;

providing a clip assembly with at least one clip removably stored in a clip cartridge;

including in one of the handle assembly and the clip assembly a pair of jaws sized and configured to receive the clip;

including in one of the handle assembly and the clip assembly an actuating mechanism for operating the jaws to position the clip relative to an object;

autoclaving the handle assembly; and

disposing of the clip assembly.

49. The method recited in Claim 48 wherein the first including step includes the step of:

attaching the jaws to the handles of the handle assembly.

50. The method recited in Claim 48 wherein the first including step includes the step of:

attaching the jaws to the cartridge of the clip assembly.

51. The method recited in Claim 48 wherein the second including step includes the step of:

attaching the actuating mechanism to the handles of the handle assembly.

52. The method recited in Claim 48 wherein the second including step includes the steps of:

attaching the actuating mechanism to the cartridge of the clip assembly.

53. The method recited in Claim 52 wherein the attaching step includes the step of removably attaching the jaws to the handles of the handle assembly.

54. A ligating clip cartridge assembly adapted to be removably mounted on a handle assembly, comprising:

a plurality of clips disposed in a train having an ultimate clip and a penultimate clip;

a tray having a proximal end and a distal end for supporting the clip train along a train path, including an operative clip position, and a gated clip position;

a pusher for moving the ultimate clip distally from the gated clip position to the operative clip position; and

a spacer having properties for moving the penultimate clip distally to the gated position.

55. The ligating clip cartridge assembly recited in Claim 54 wherein the spacer has an elongated state with a first length and a contracted state with a second length less than the first length.

56. The ligating clip cartridge assembly recited in Claim 55 wherein the spacer has

properties for moving from the elongated state to the contracted state as the pusher moves the ultimate clip from the gated clip position to the operative clip position.

57. The ligating clip cartridge assembly recited in Claim 54 wherein the clip train moves only distally.

58. The ligating clip cartridge assembly recited in Claim 54 wherein the pusher has a distal end that is retractable to a position proximal of the penultimate clip.

59. The ligating clip cartridge assembly recited in Claim 58 wherein an inclined flange at the distal end of the pusher causes the pusher to cam upwardly and proximally on the penultimate clip.

60. The ligating clip cartridge assembly recited in Claim 54 wherein:

the spacer has a proximal end and a distal end; and

the proximal end of the spacer ratchets on the pusher with progressive distal positions along the pusher.

61. The ligating clip cartridge assembly recited in Claim 55 wherein the spacer generally maintains its elongated state until the penultimate clip arrives at the gated clip position.

62. The ligating clip cartridge assembly recited in Claim 54 wherein:

the clips in the clip train have a normal spacing; and

the ultimate clip is moved distally by the pusher to provide the ultimate clip and the penultimate clip with a separation greater than the normal spacing.

63. The ligating clip cartridge assembly recited in Claim 54, further comprising:

a pair of jaws movable between an open position and a closed position; and

a delay mechanism for holding the pusher in a retracted position until the jaws are in the open position.

64. The ligating clip cartridge assembly recited in Claim 63 wherein the delay mechanism includes a spring biasing the pusher in a distal direction.

65. The ligating clip cartridge assembly recited in Claim 54 wherein the pusher ratchets along the tray with progressive distal positions of the pusher relative to the tray.

66. A method for advancing each of a plurality of ligating clips including an ultimate clip and a penultimate clip, into an operative position, the method including the steps of:

providing a tray to support the clips along a clip train path extending between a distal end and a proximal end of the tray, the tray having a gate positioned along the clip train path;

pushing the ultimate clip to the operative position; and

during the pushing step moving the clip train distally with a spacer of variable length until the penultimate clip arrives at the gate of the tray.

67. The method recited in Claim 66, wherein:

the pushing step is longer in duration than the moving step by an extension; and

during the extension, the length of the spacer decreases.

68. The method recited in Claim 67, further comprising:

retracting the pusher over the penultimate clip; and

during the retracting step, camming the pusher on the penultimate clip.

69. The method recited in Claim 68 wherein during the retracting step, the length of the spacer increases.

70. The method recited in Claim 69 wherein, during the retracting step, the method further comprises the step of retracting a distal end of the spacer distally relative to the pusher.

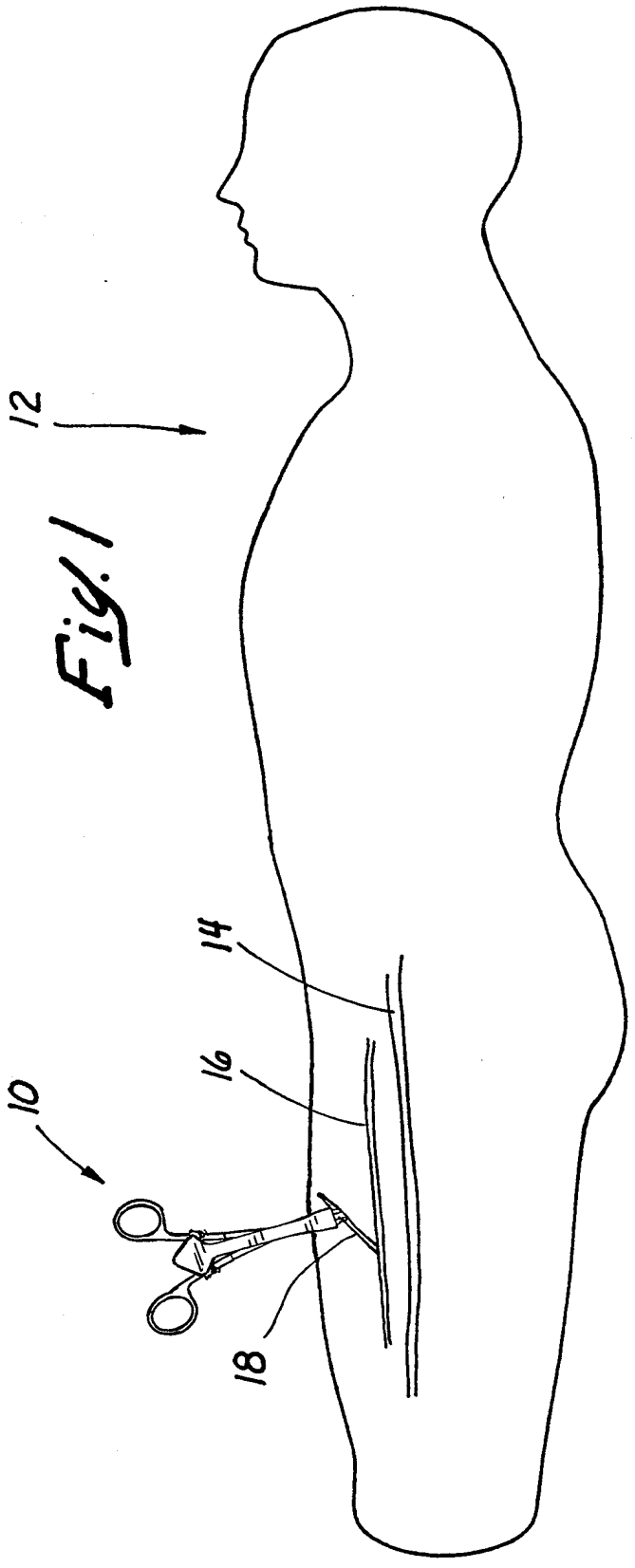


Fig. 1

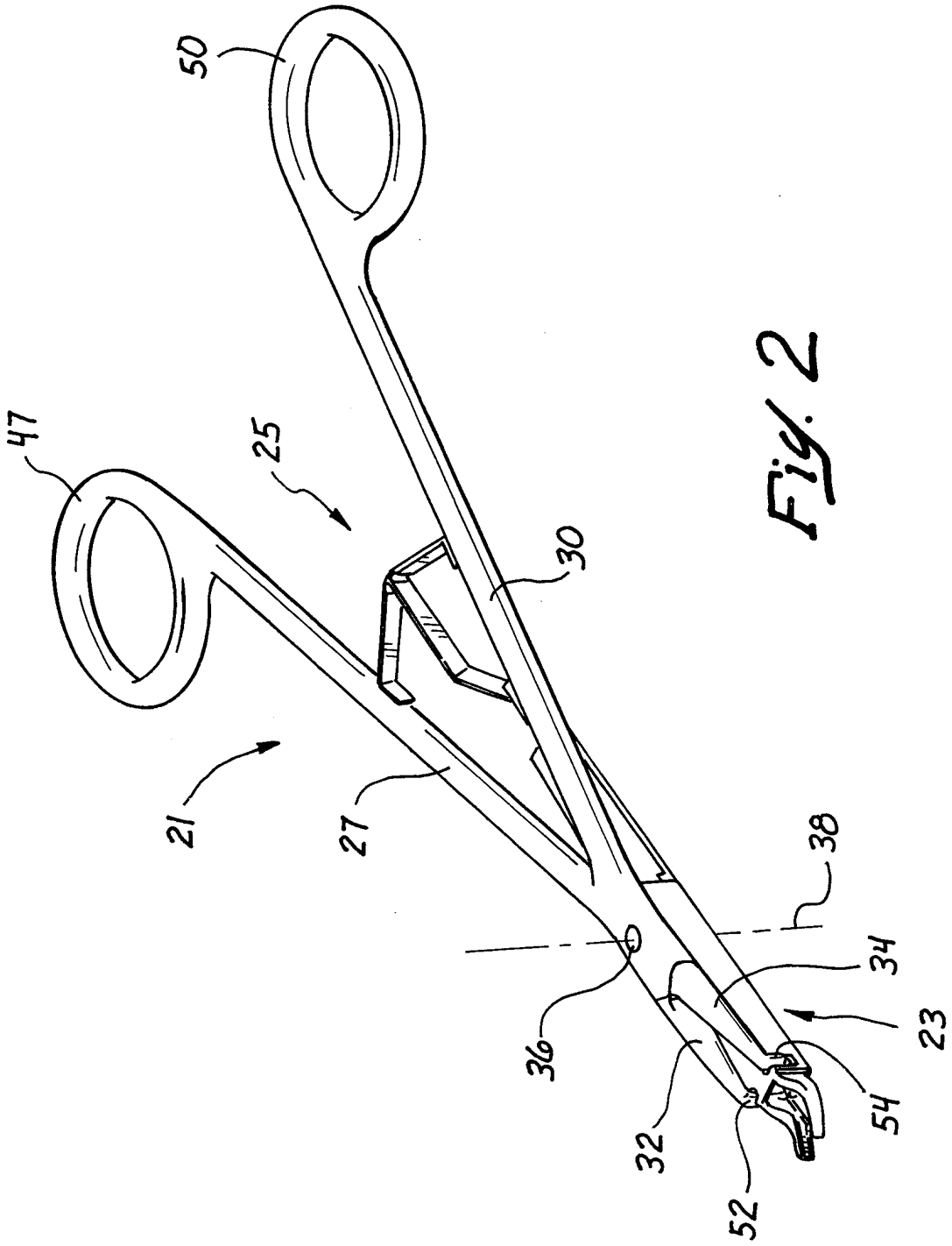


Fig. 2

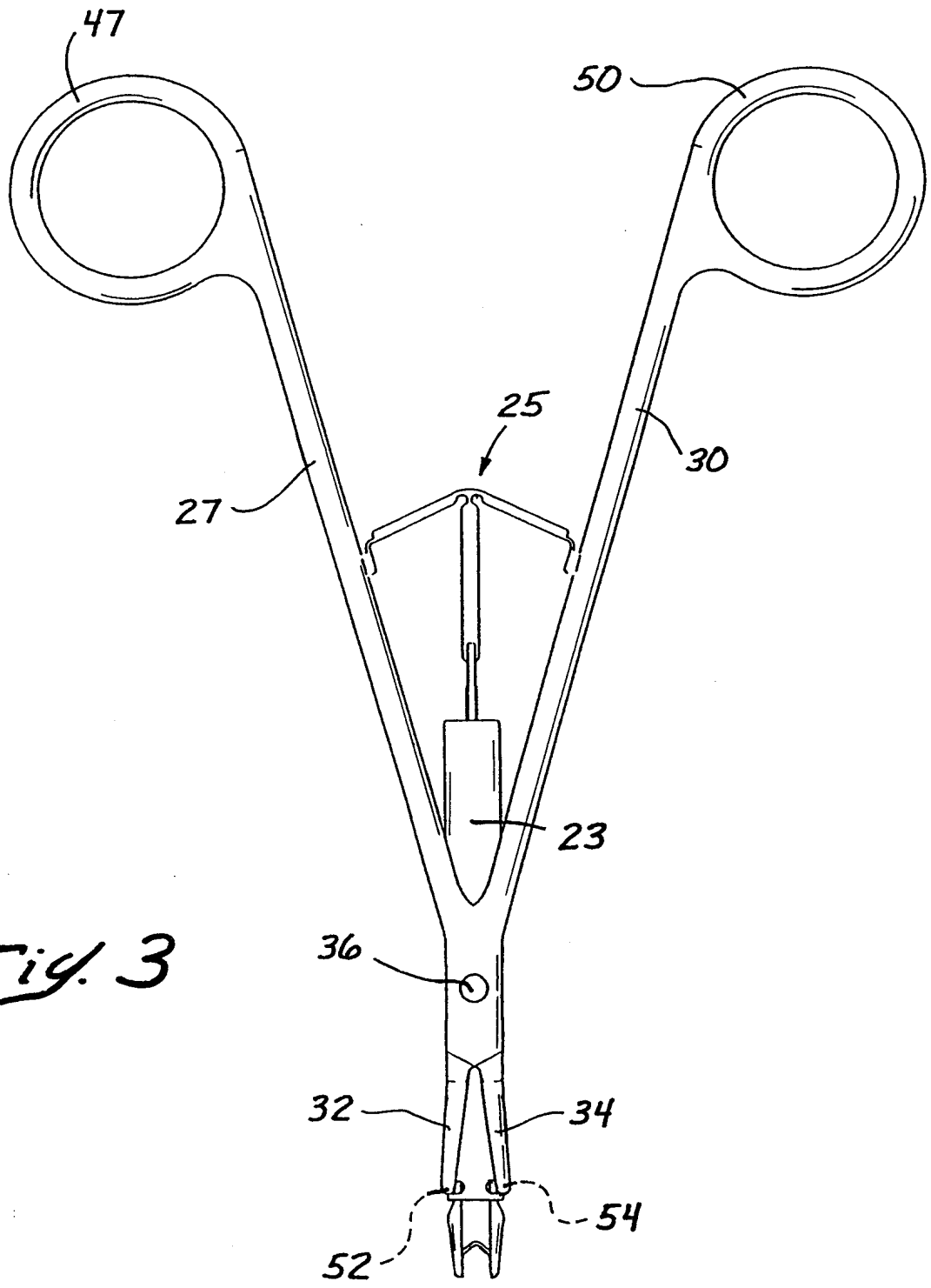
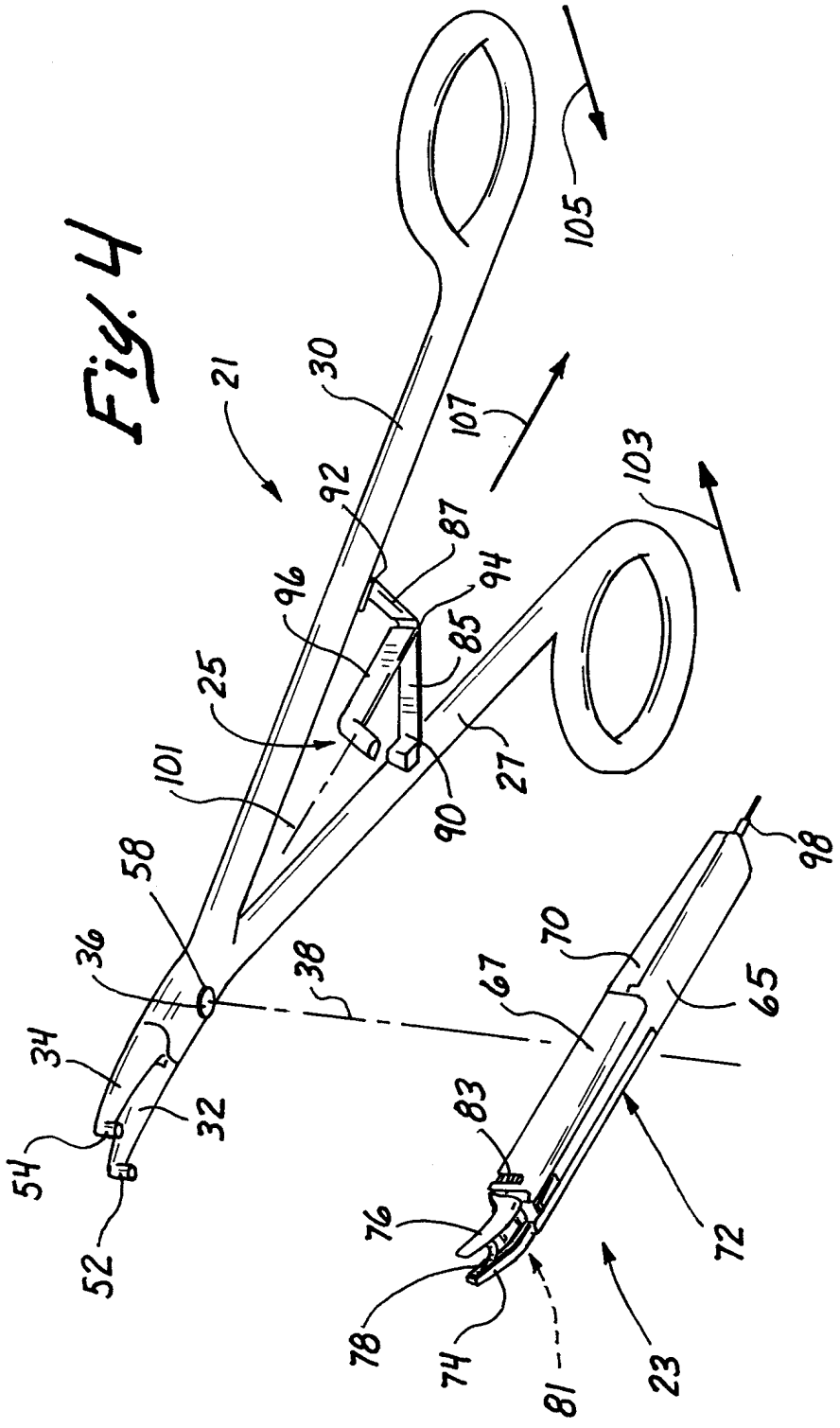


Fig. 3

Fig. 4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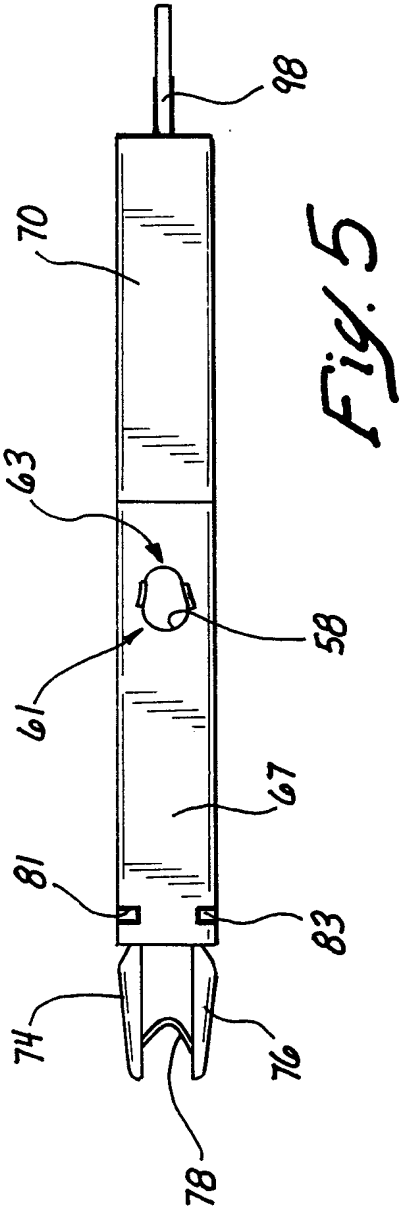


Fig. 5

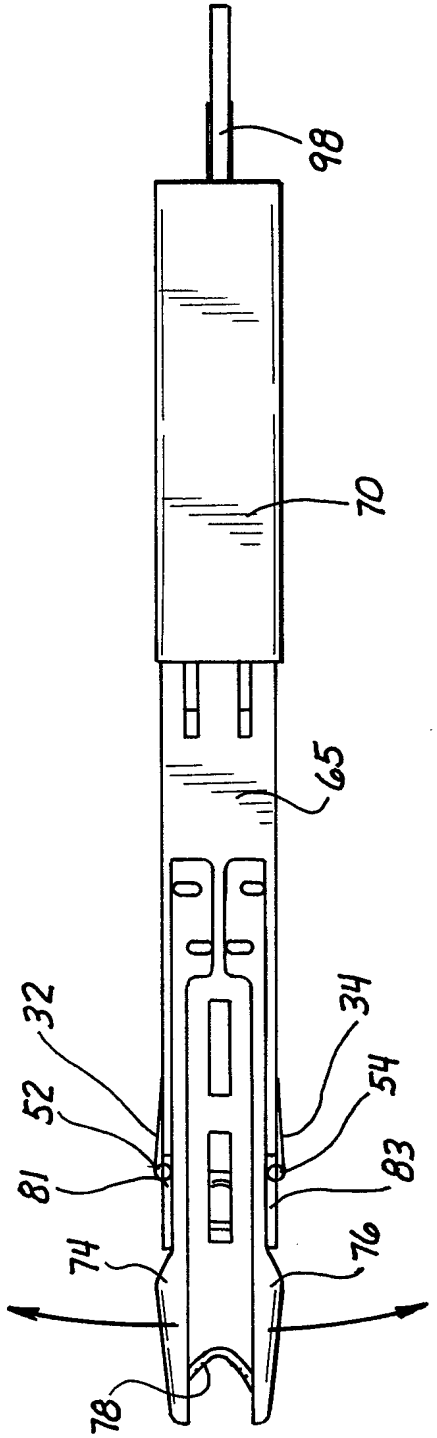
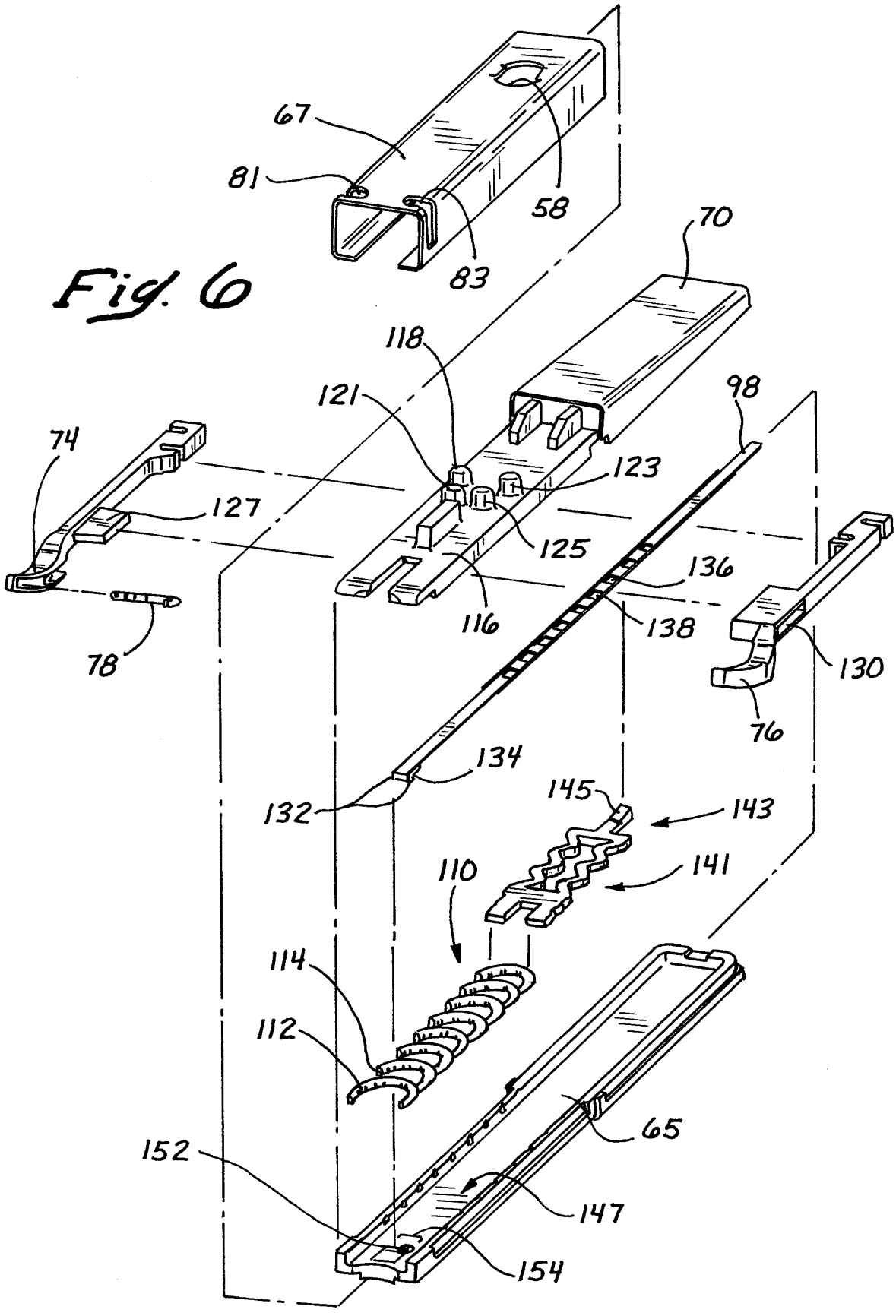


Fig. 7

Fig. 6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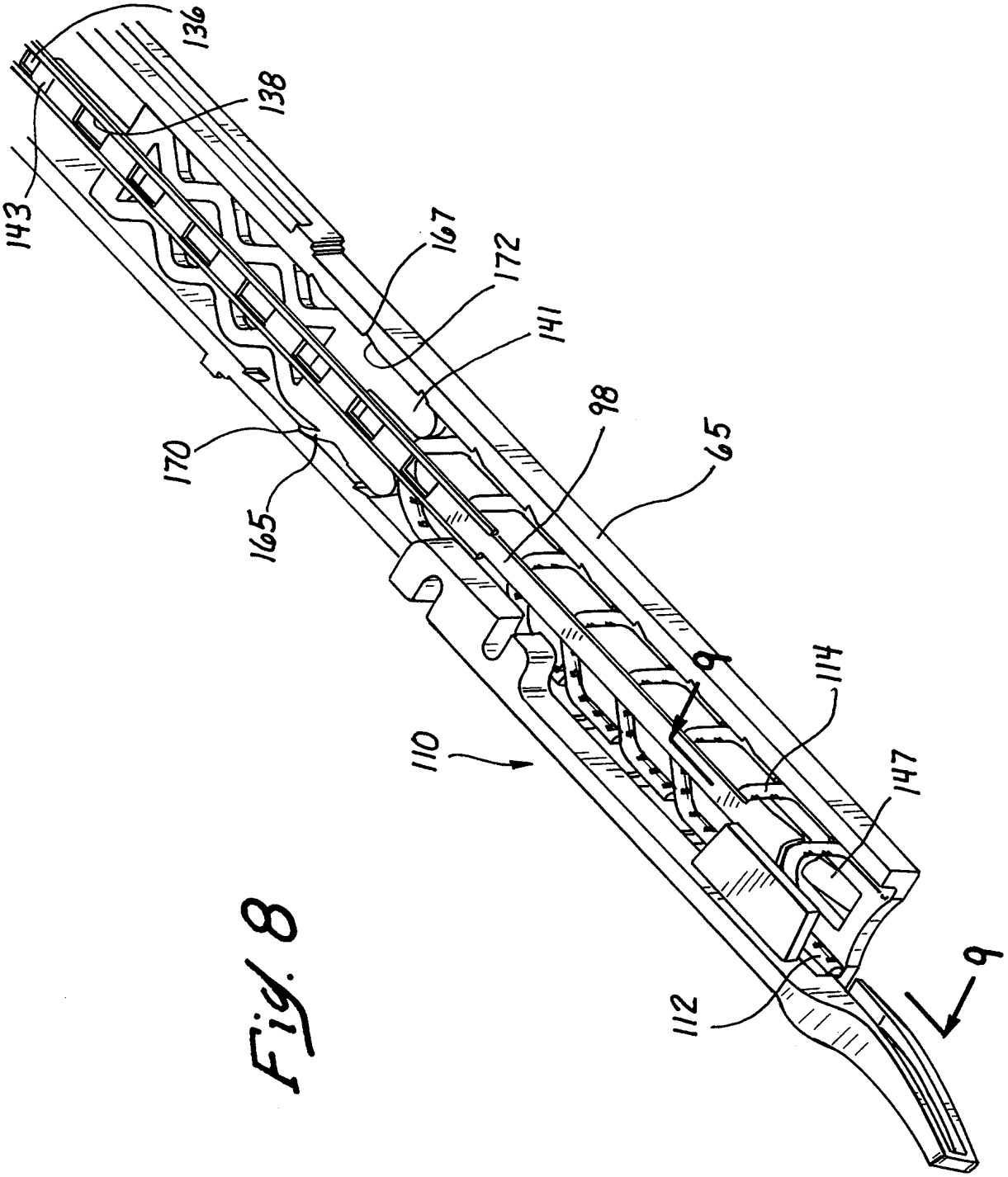


Fig. 8

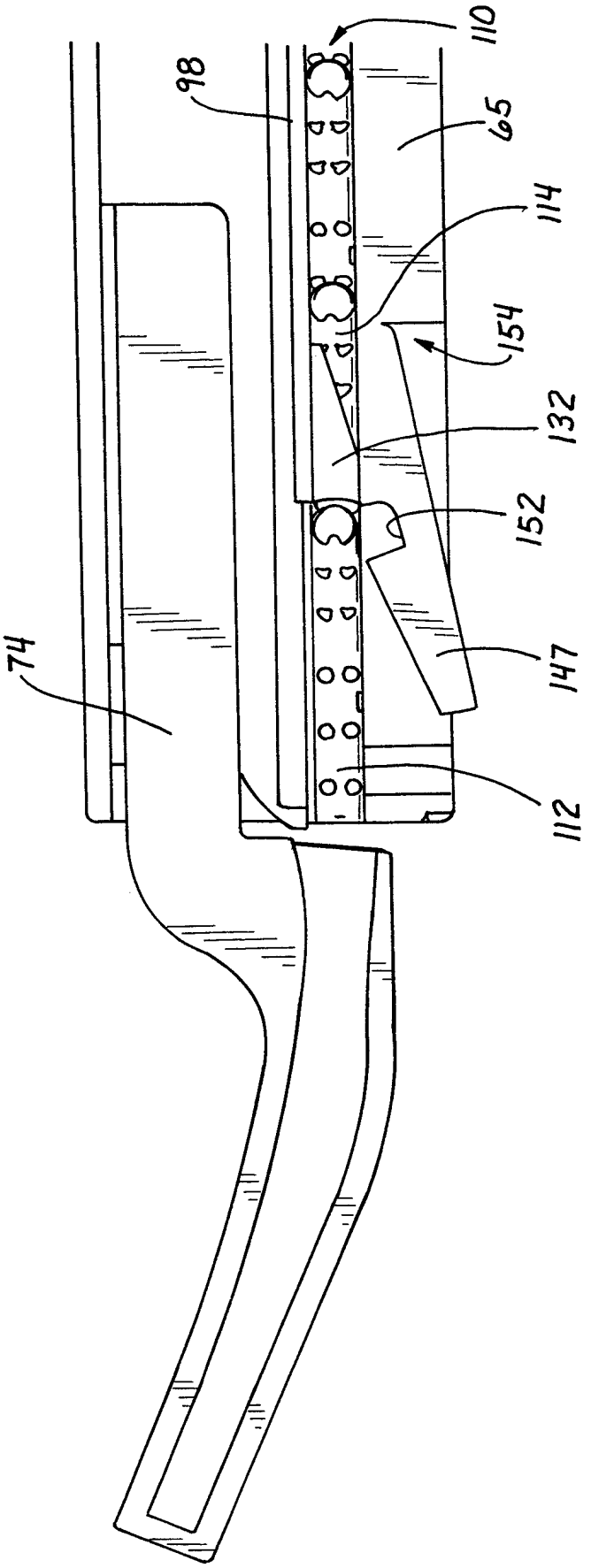


Fig. 9

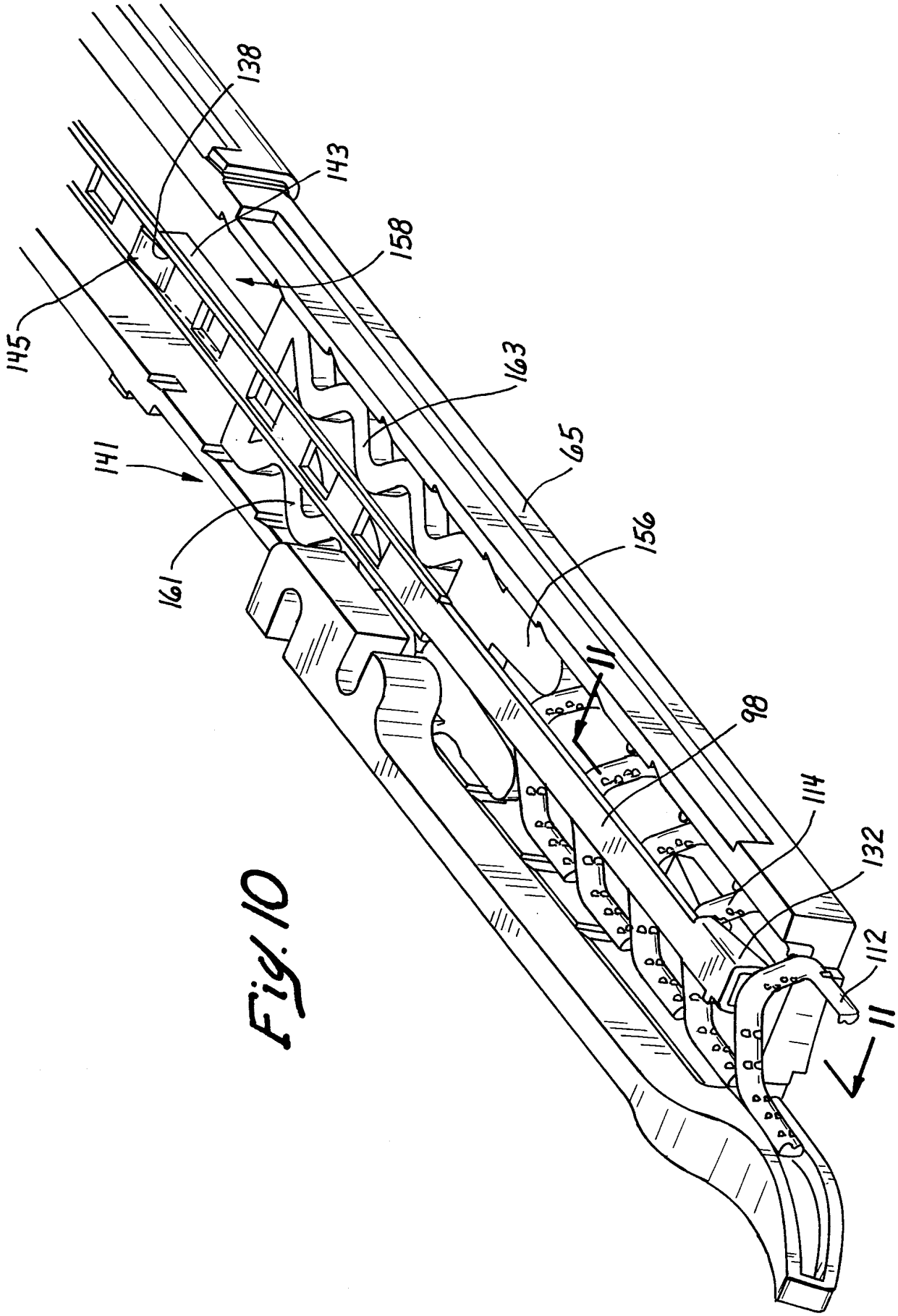


Fig. 10

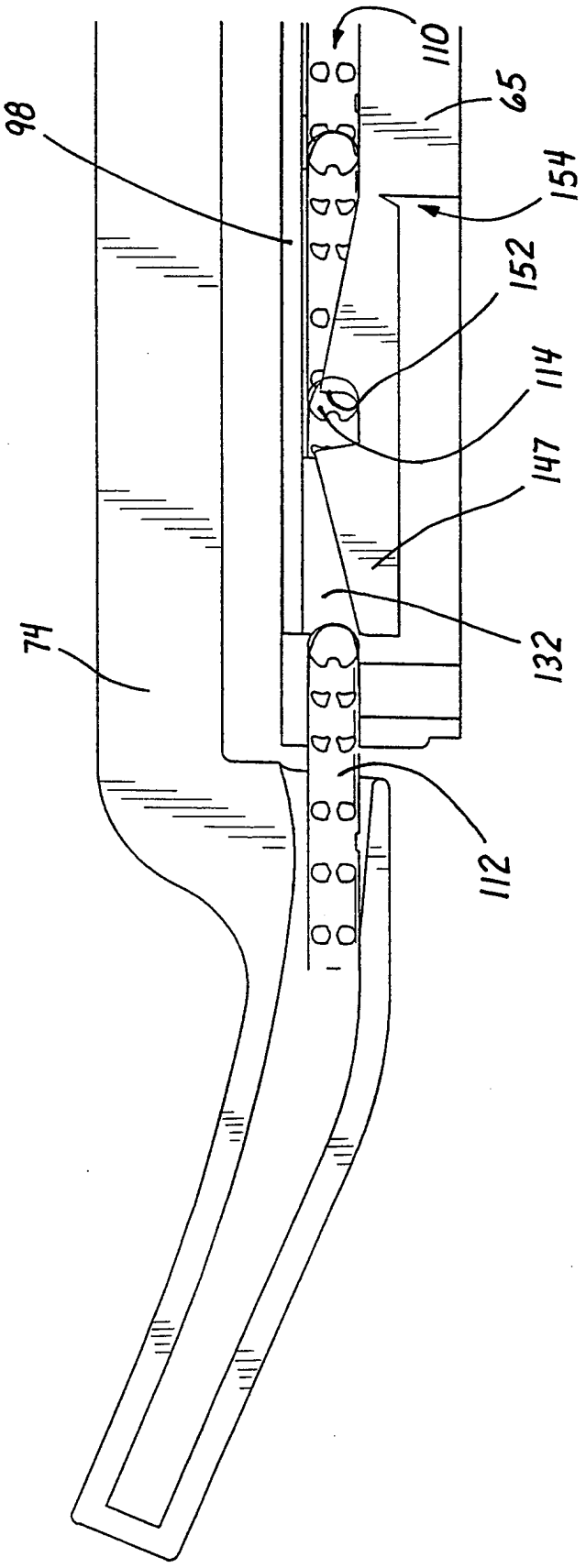


Fig. 11

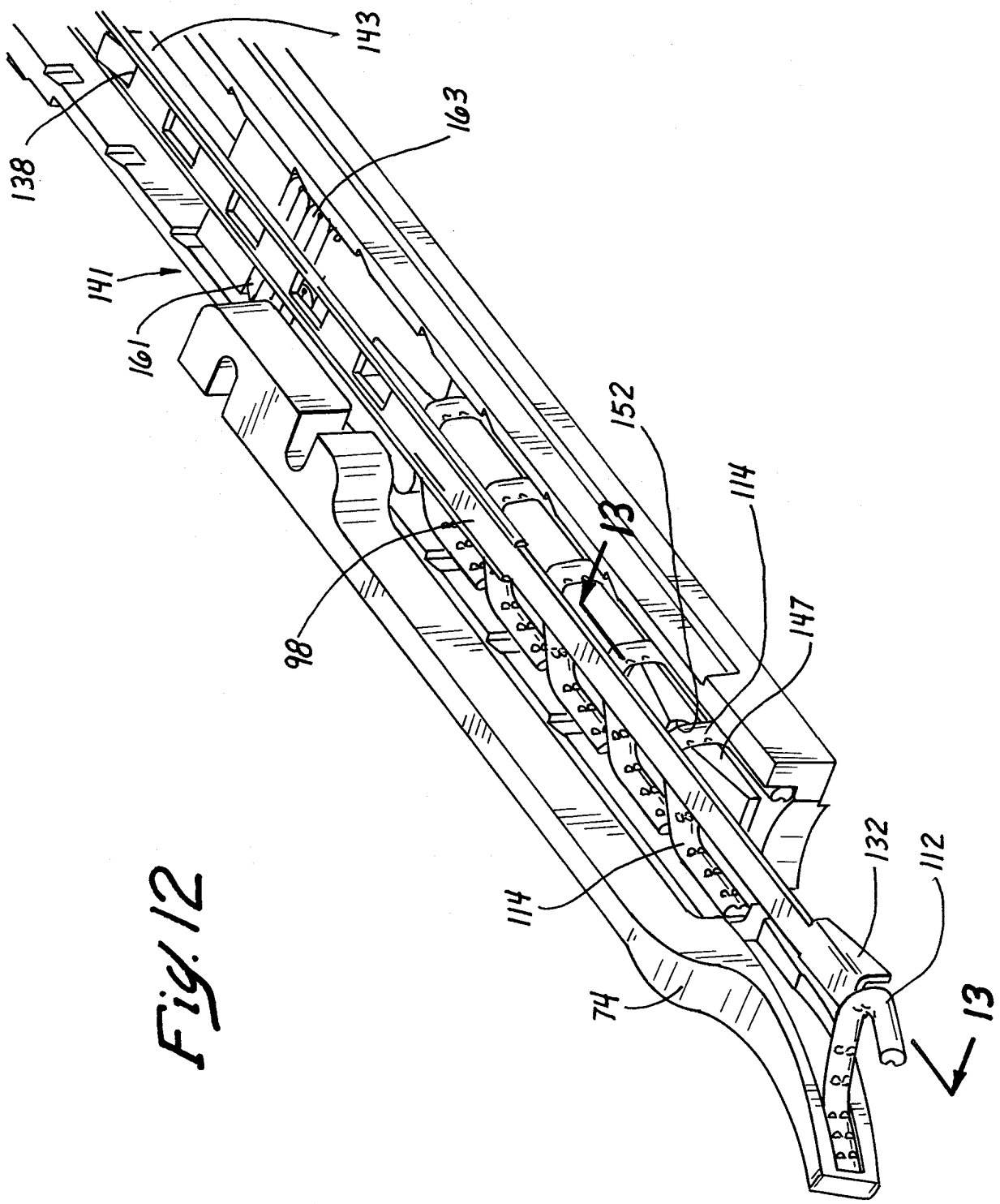
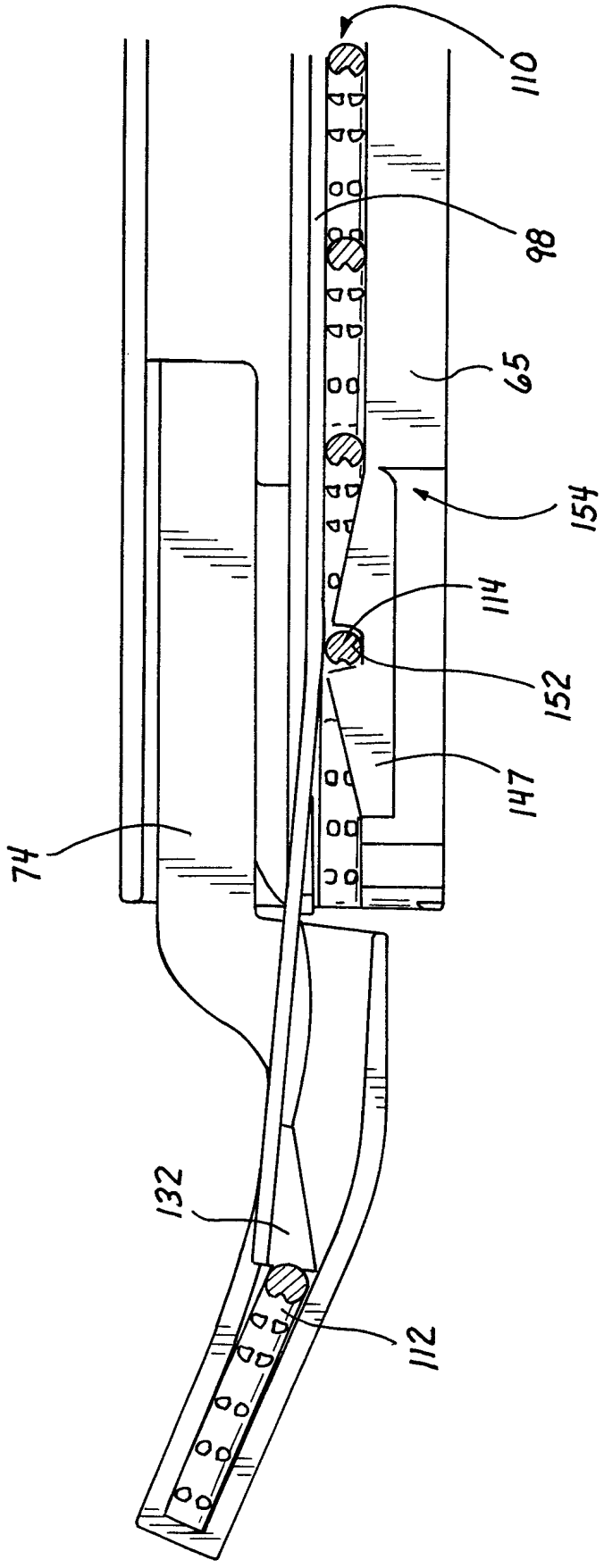


Fig. 12

Fig. 13



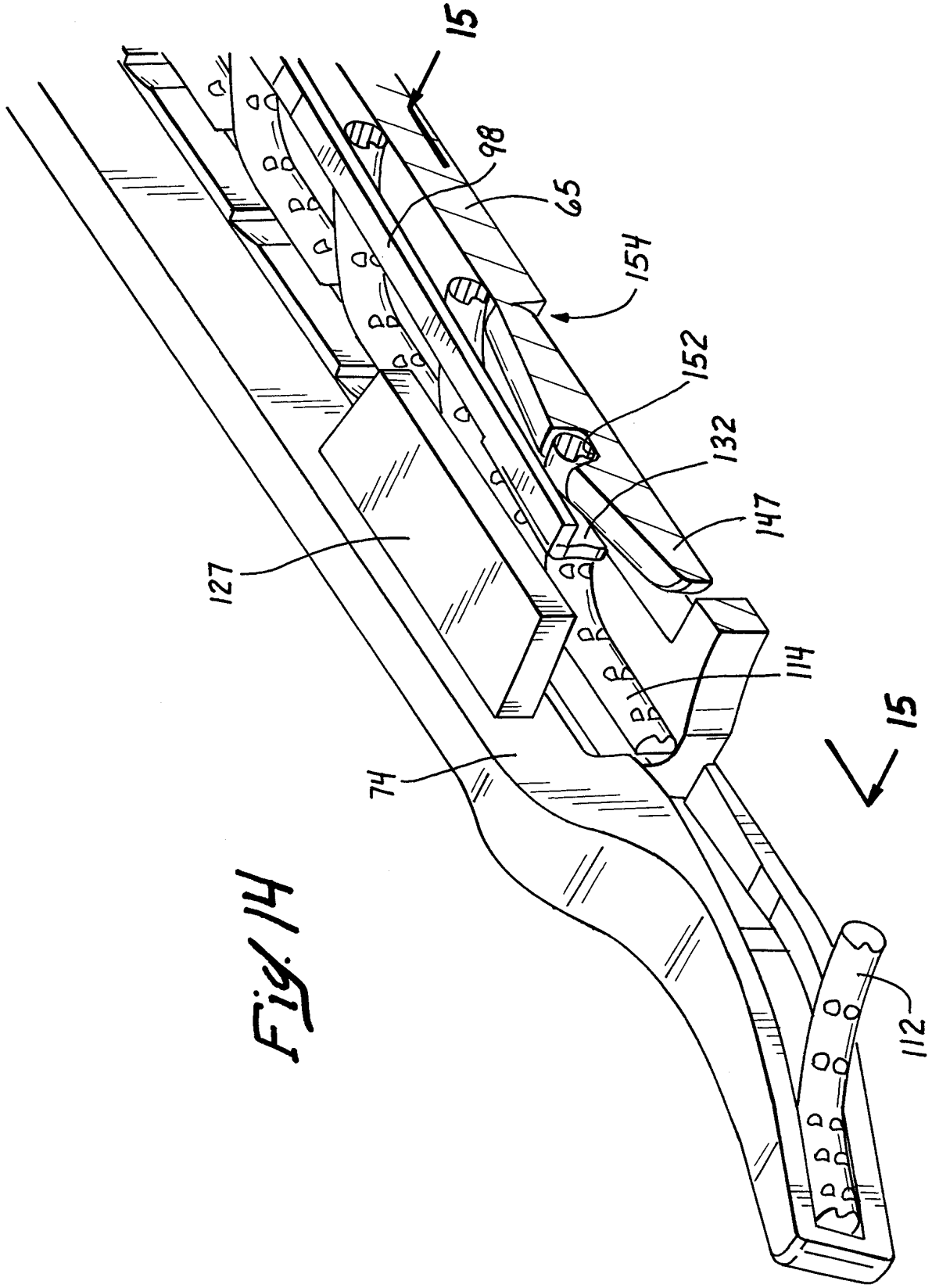


Fig. 14

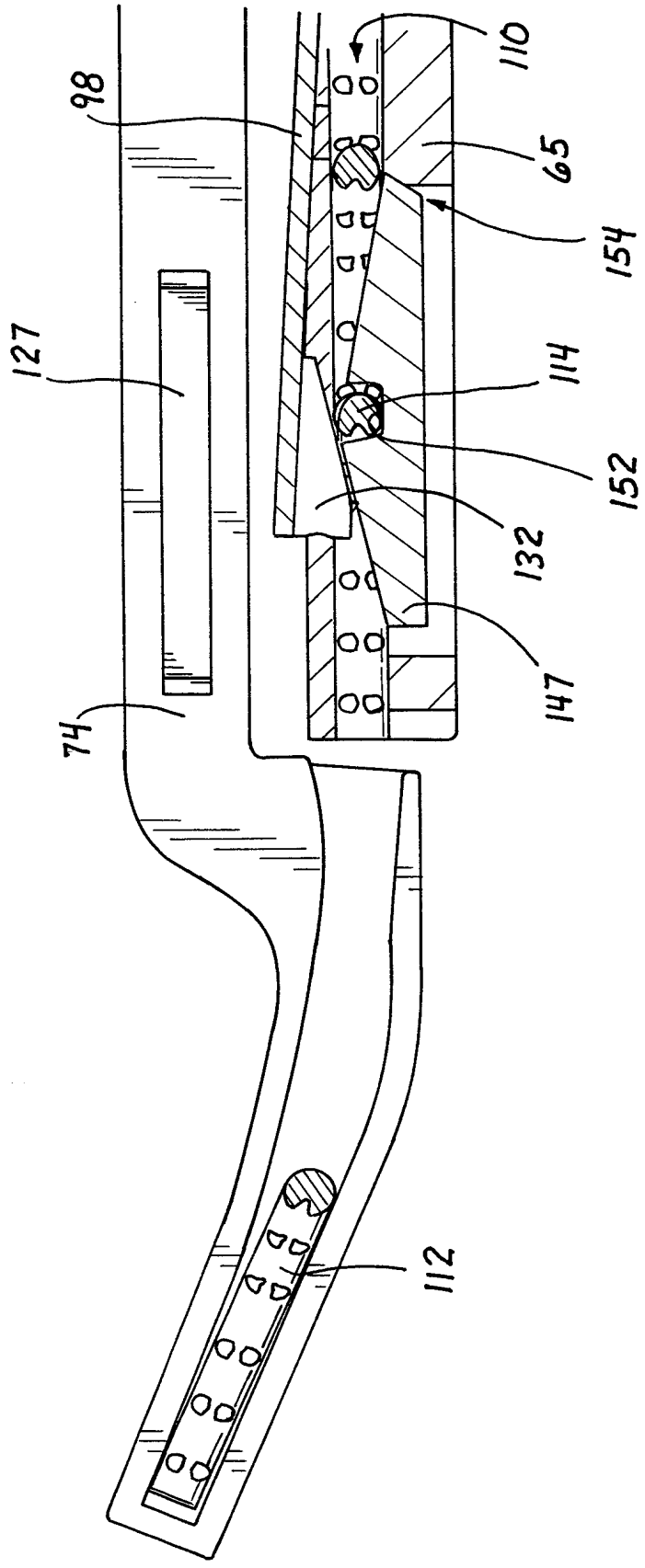
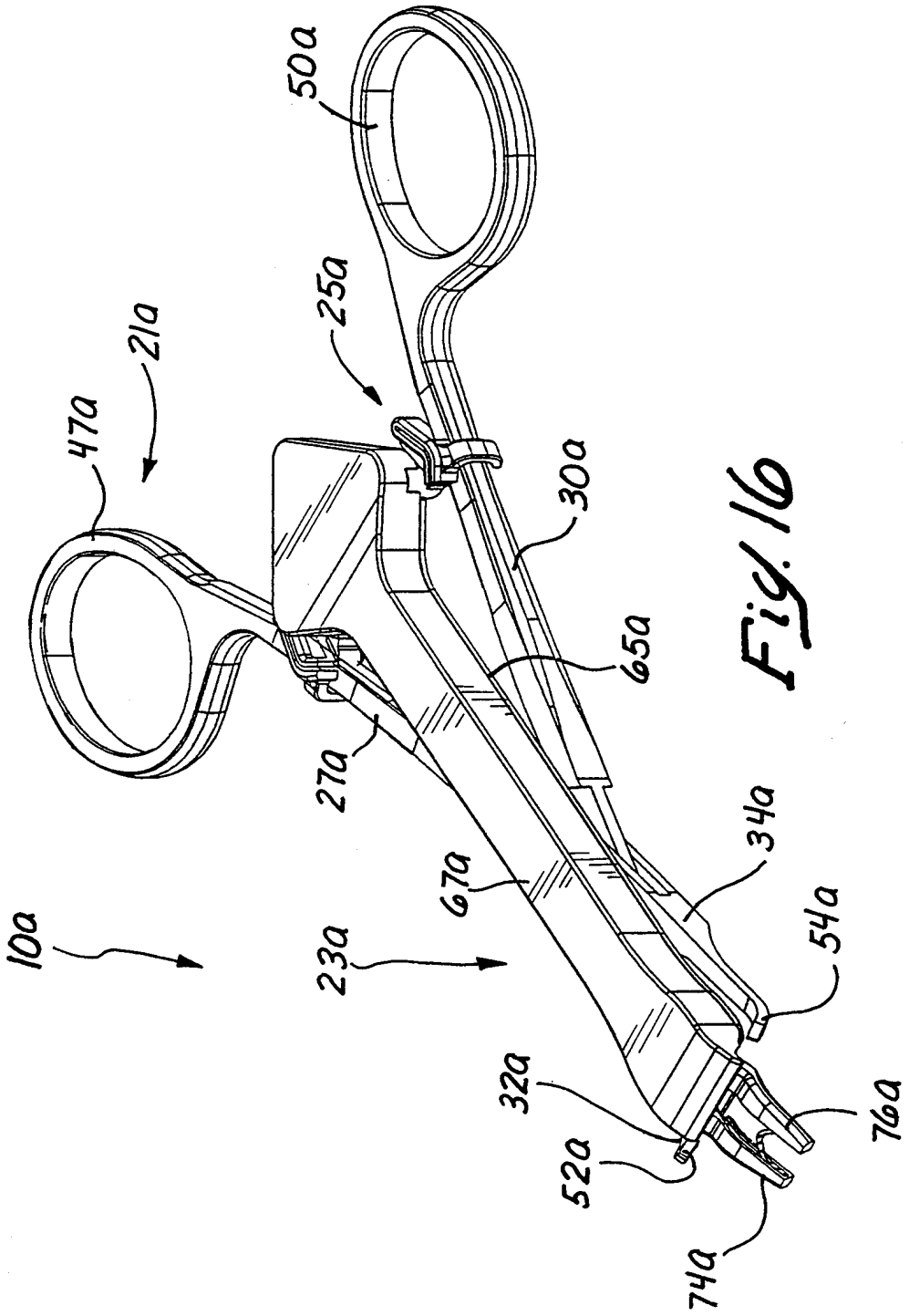


Fig. 15



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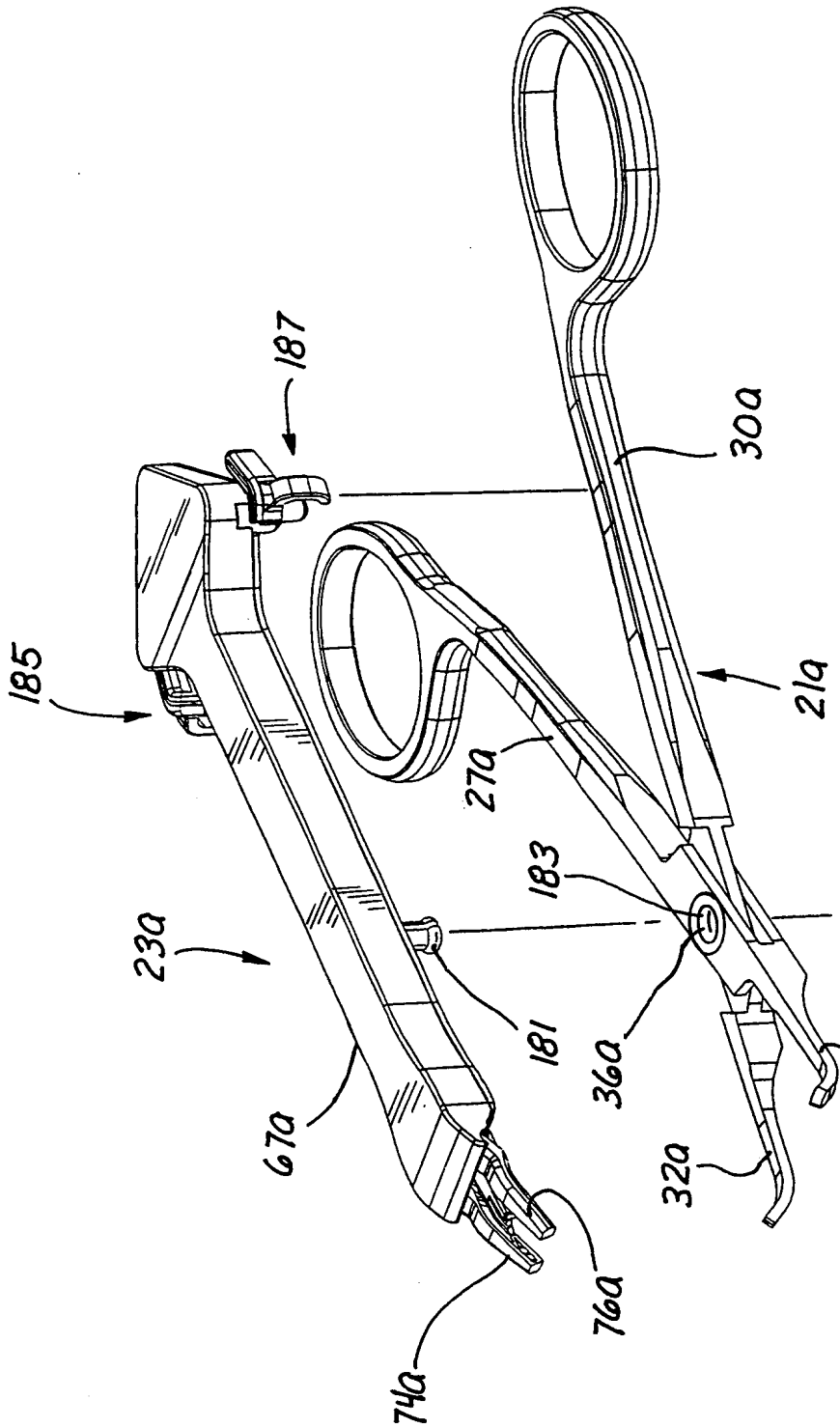
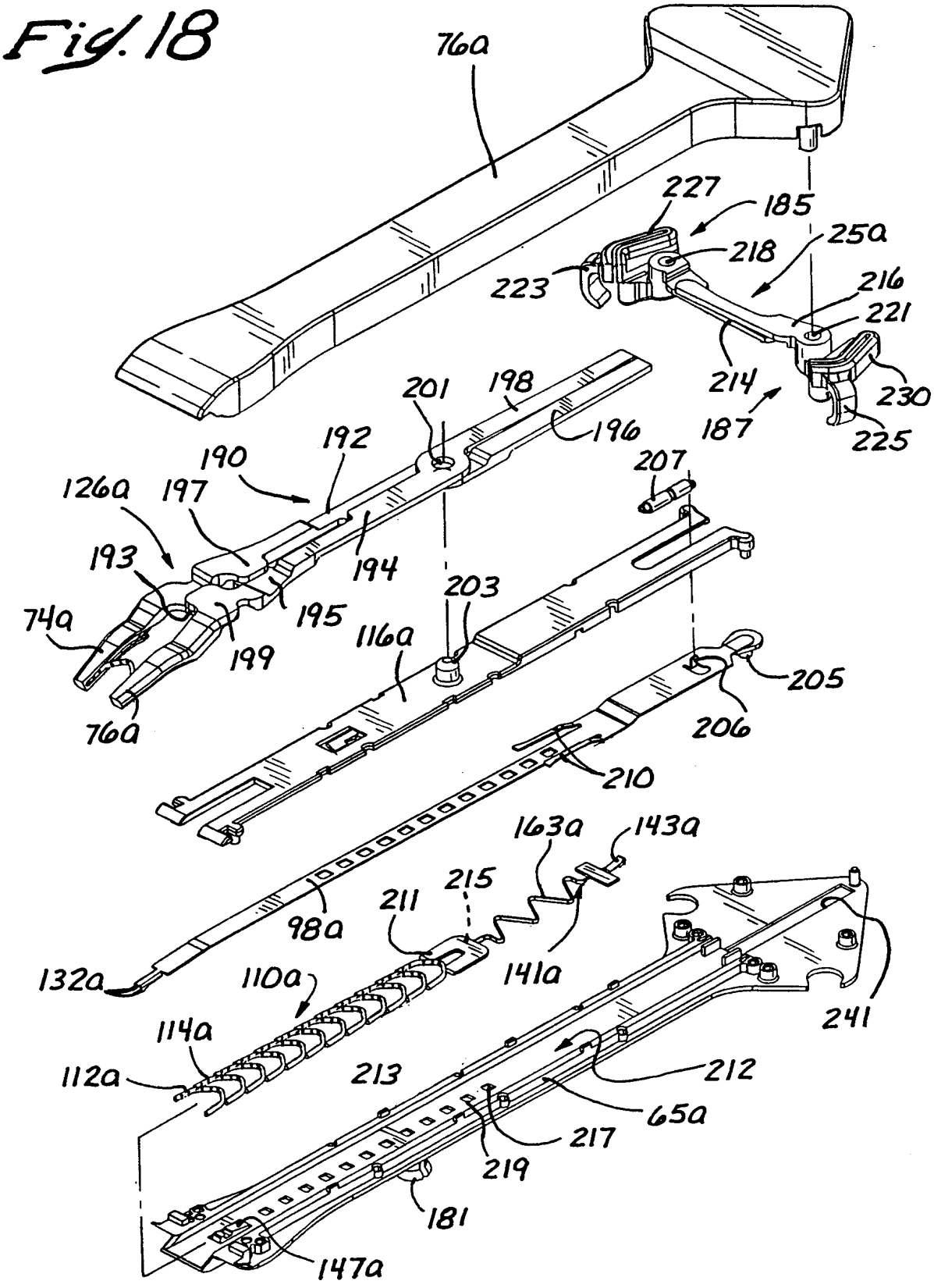


Fig. 17

Fig. 18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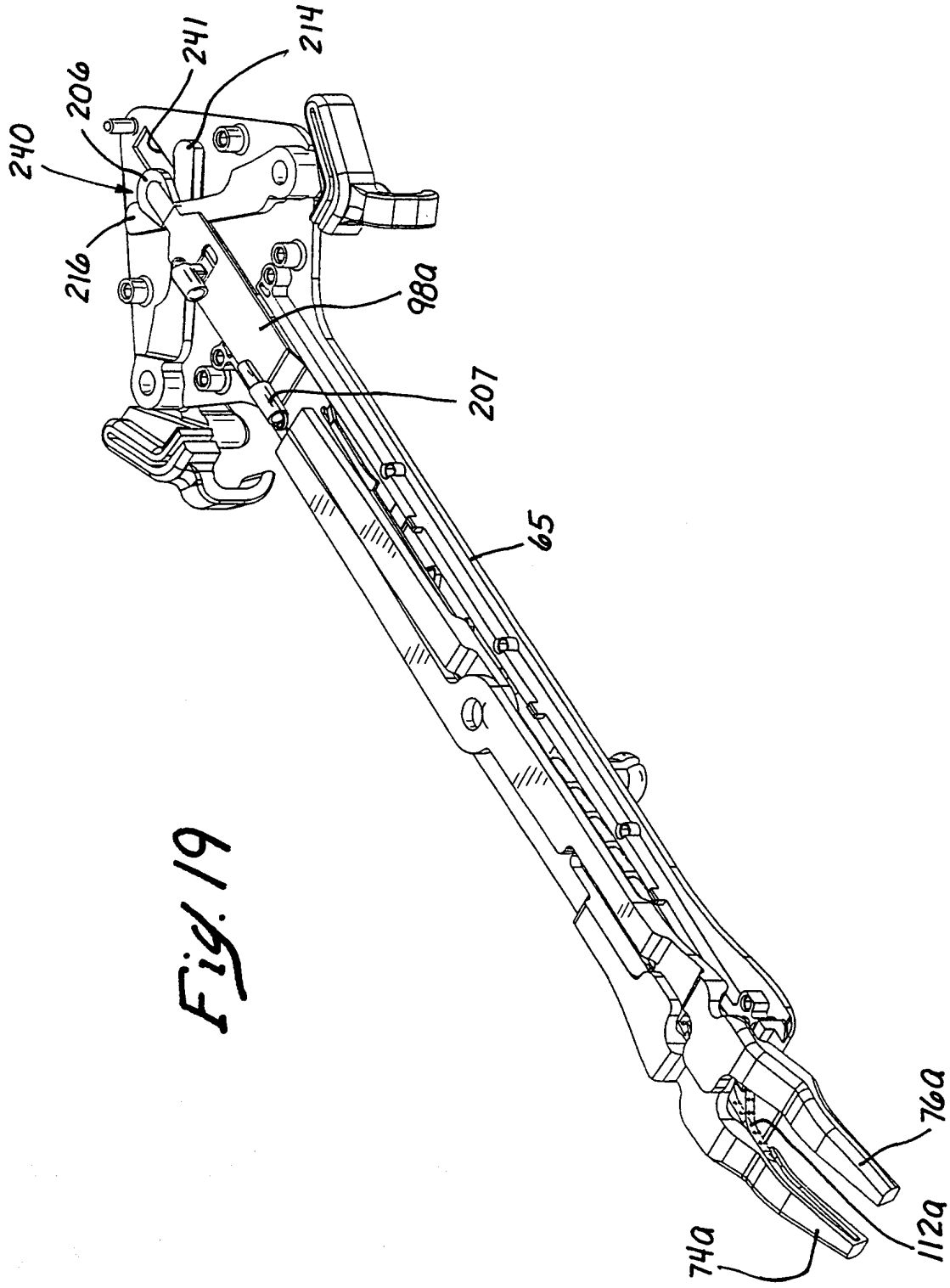

Fig. 19

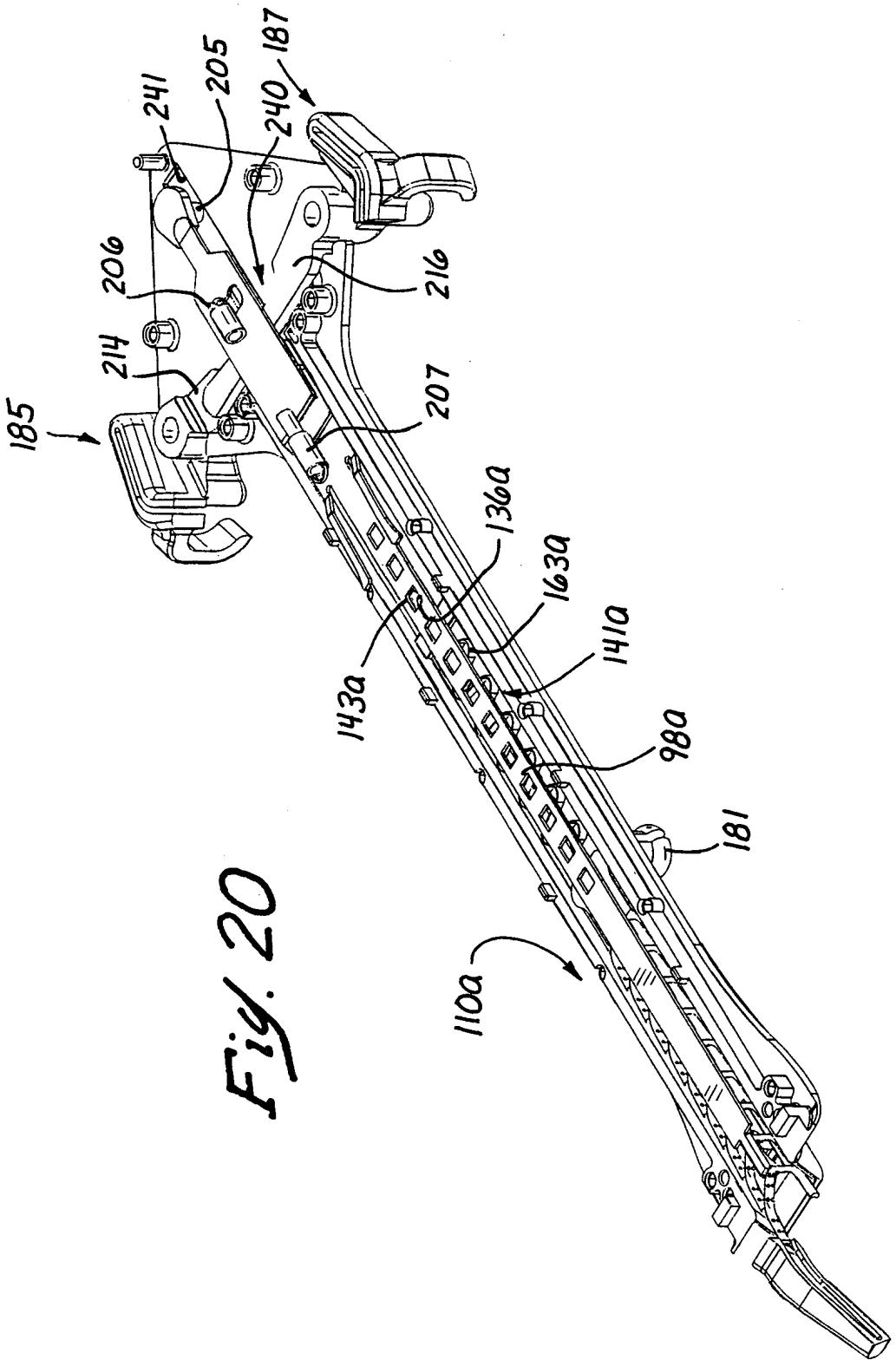
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Fig. 20

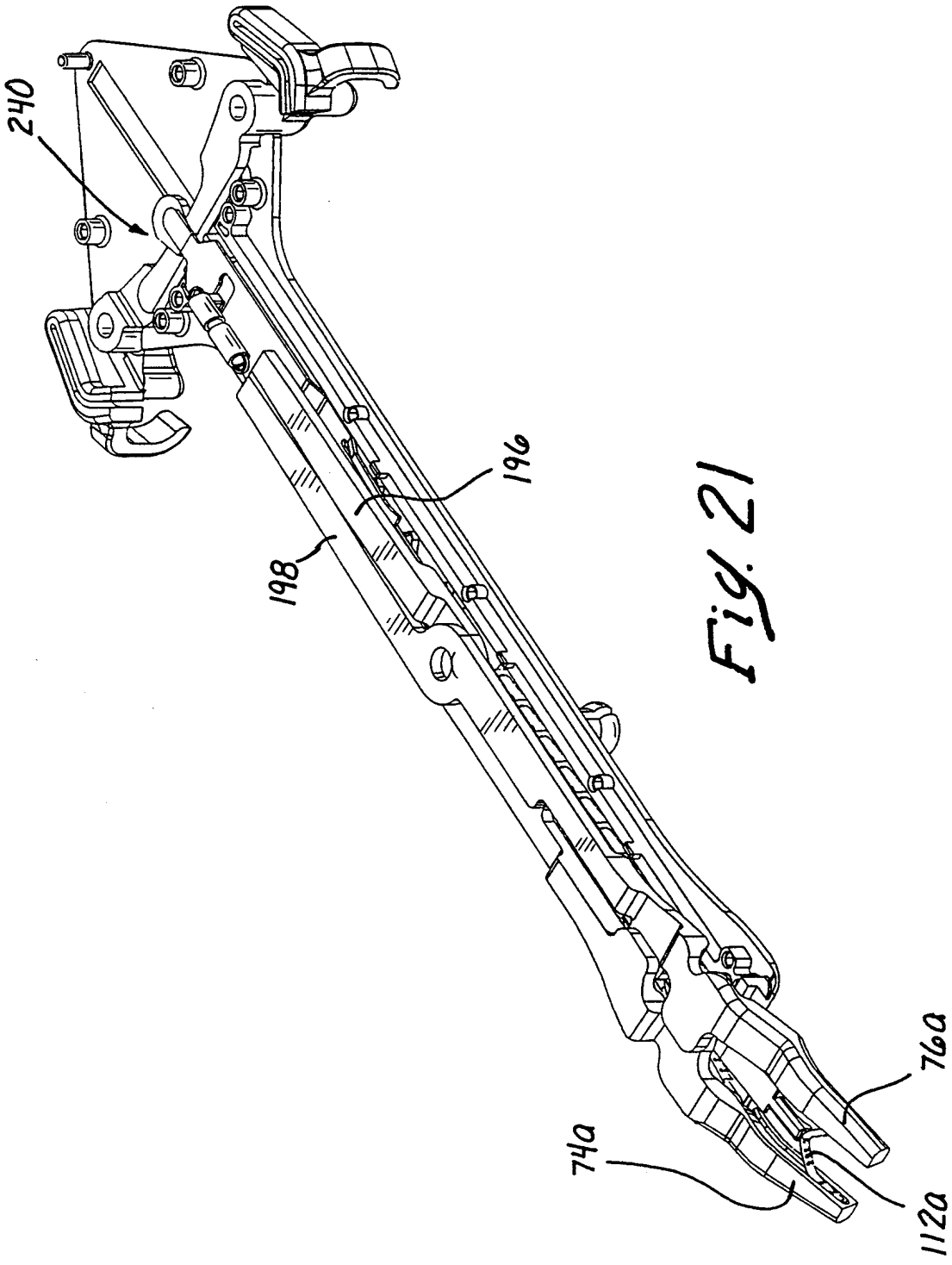

Fig. 21

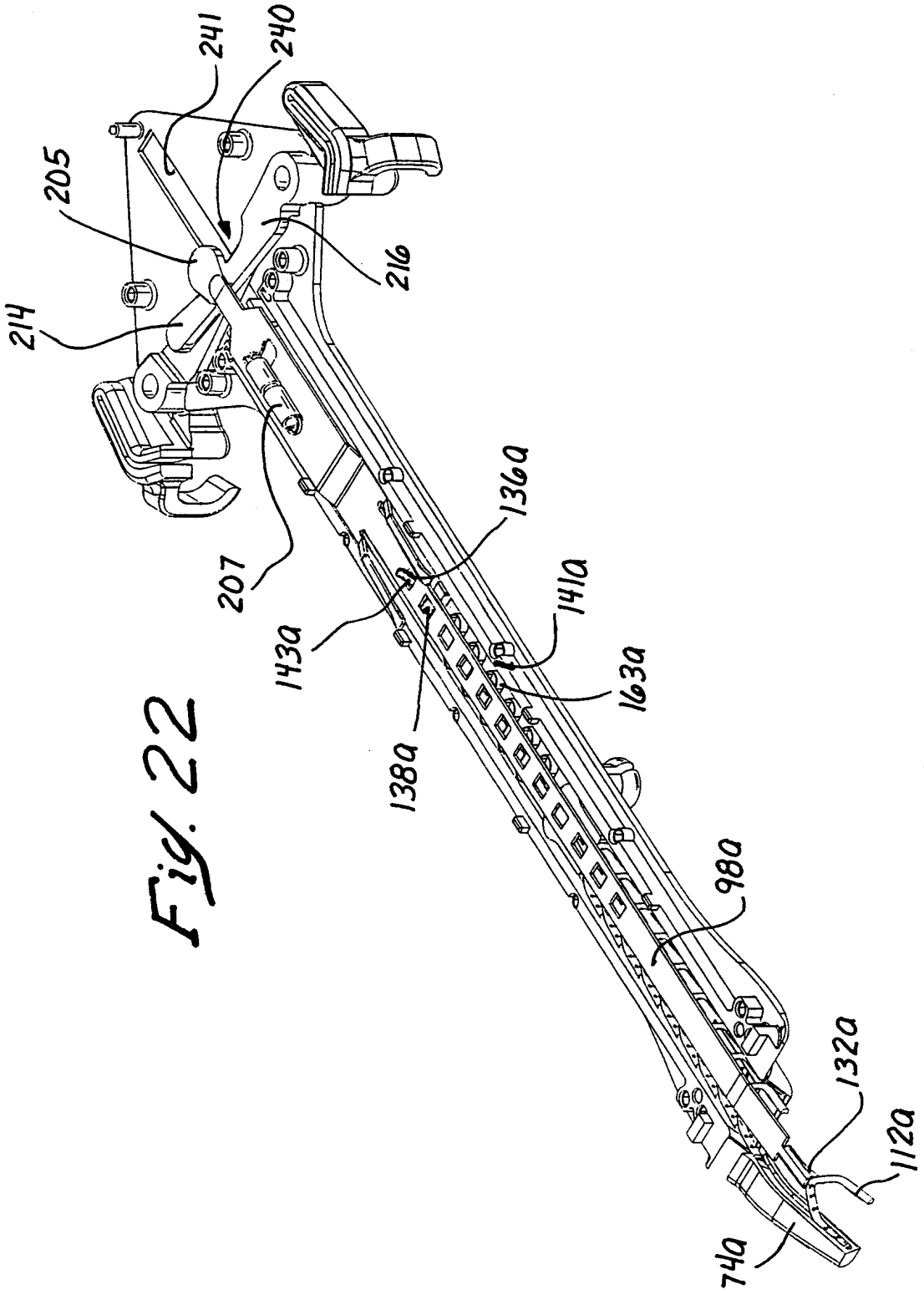
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Fig. 22

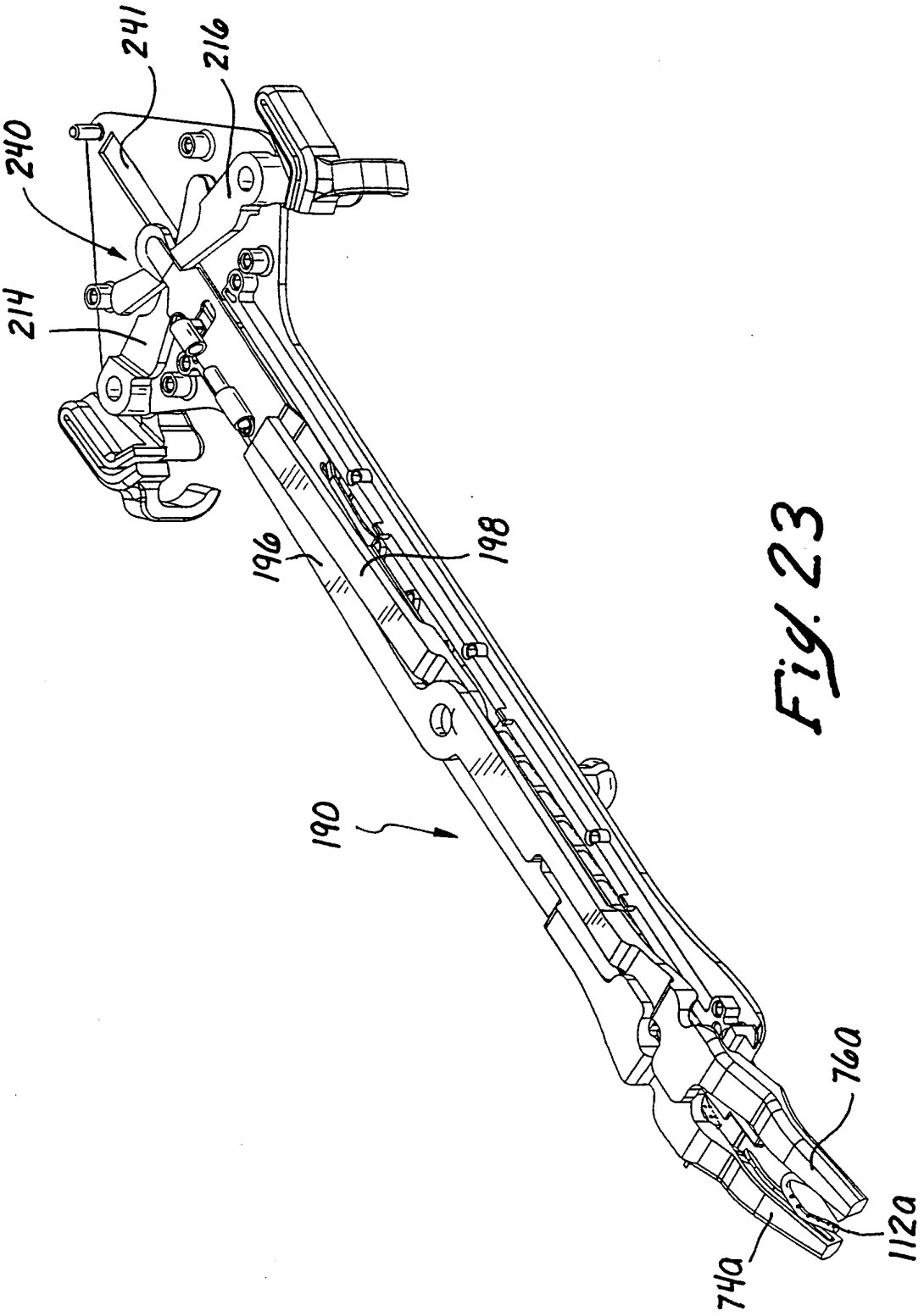

Fig. 23

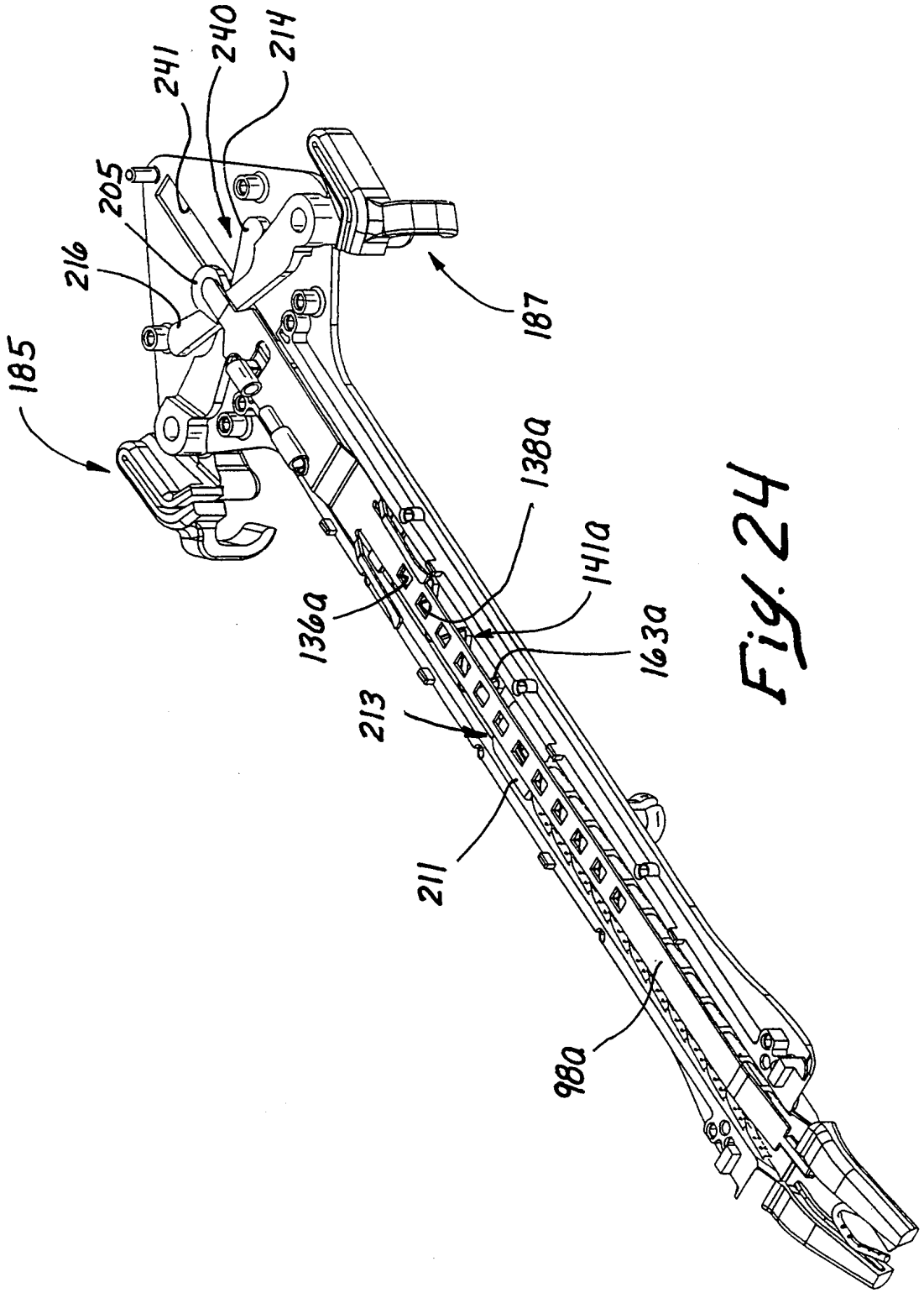

Fig. 24

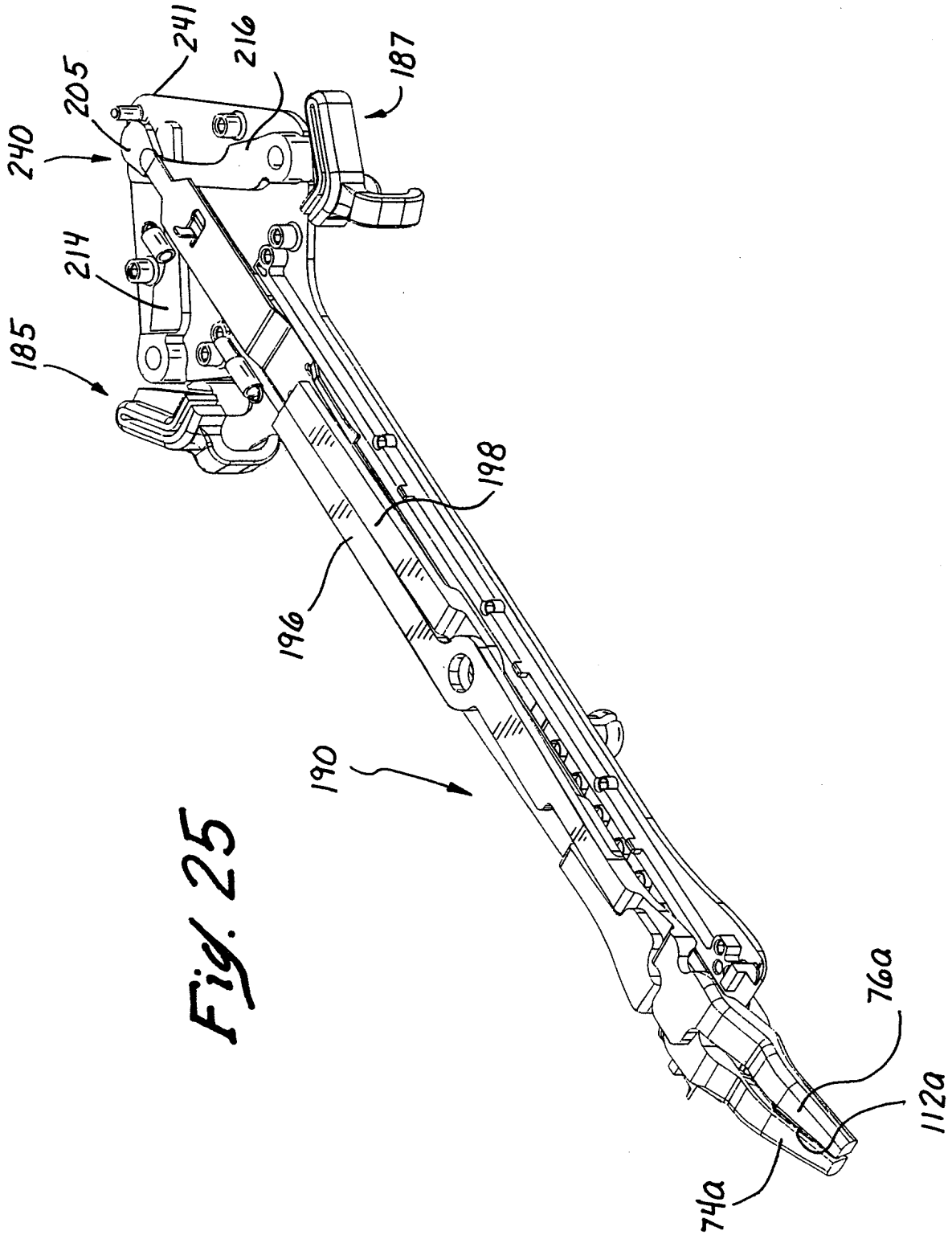

Fig. 25

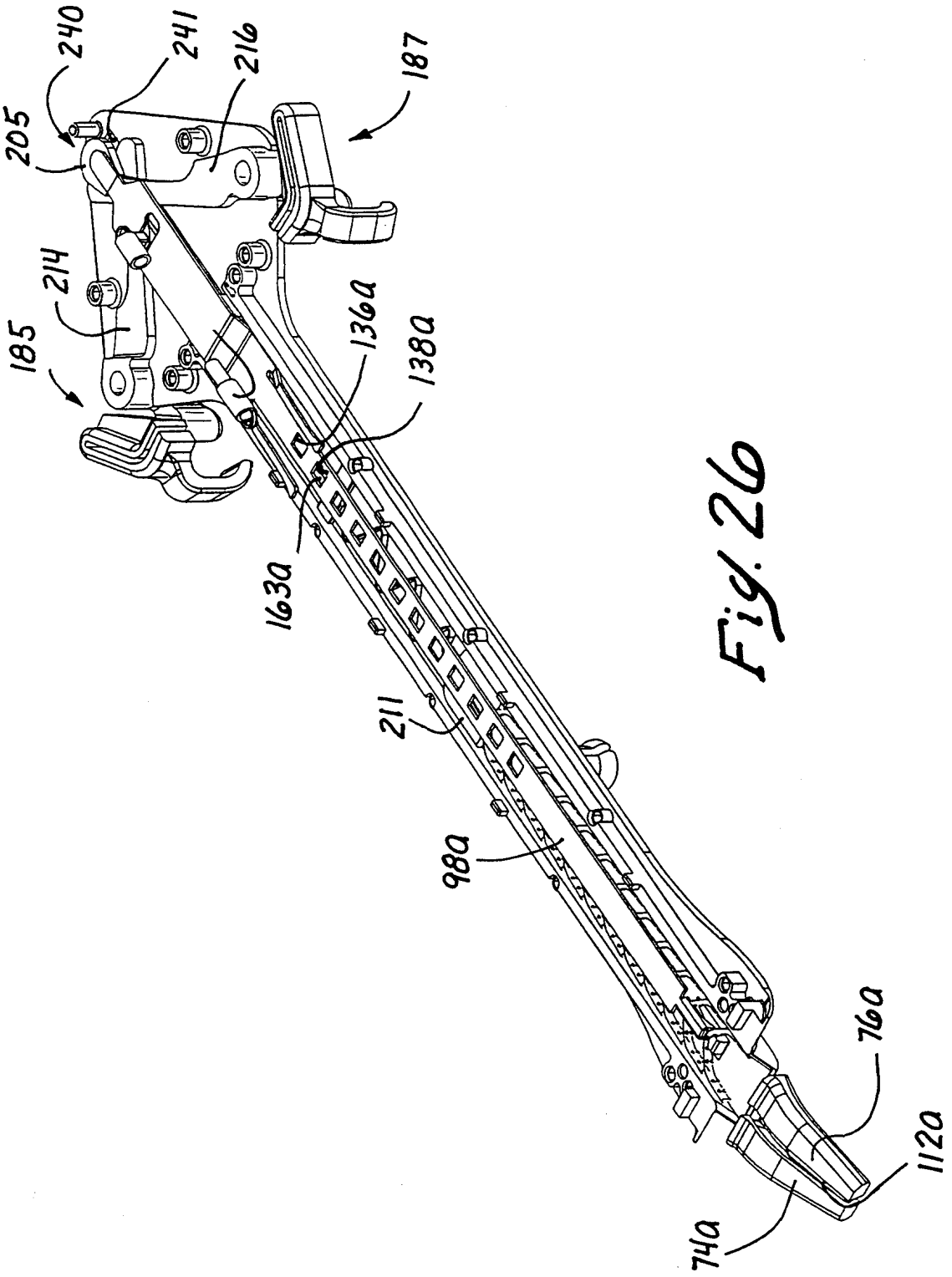

Fig. 26

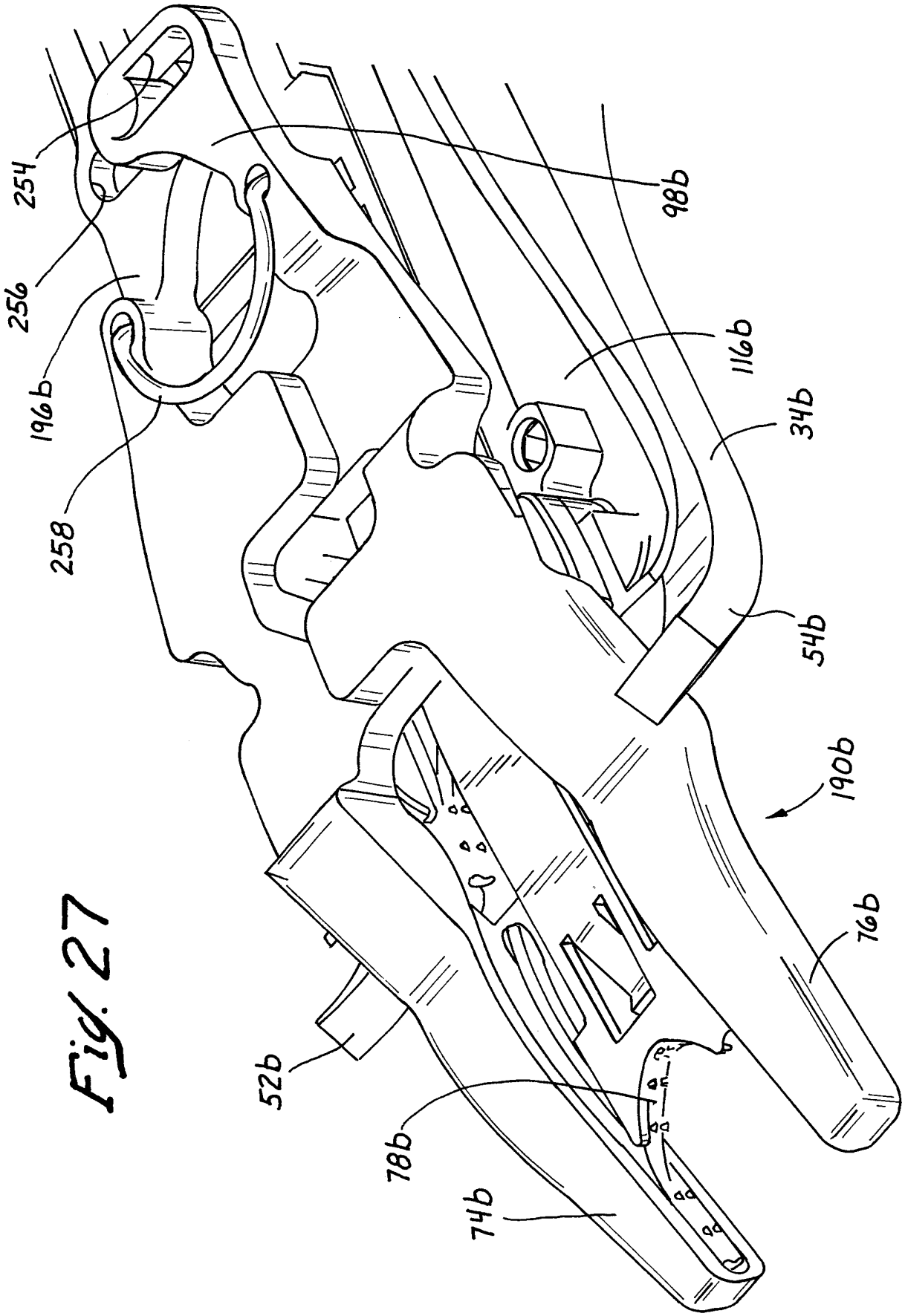

Fig. 27

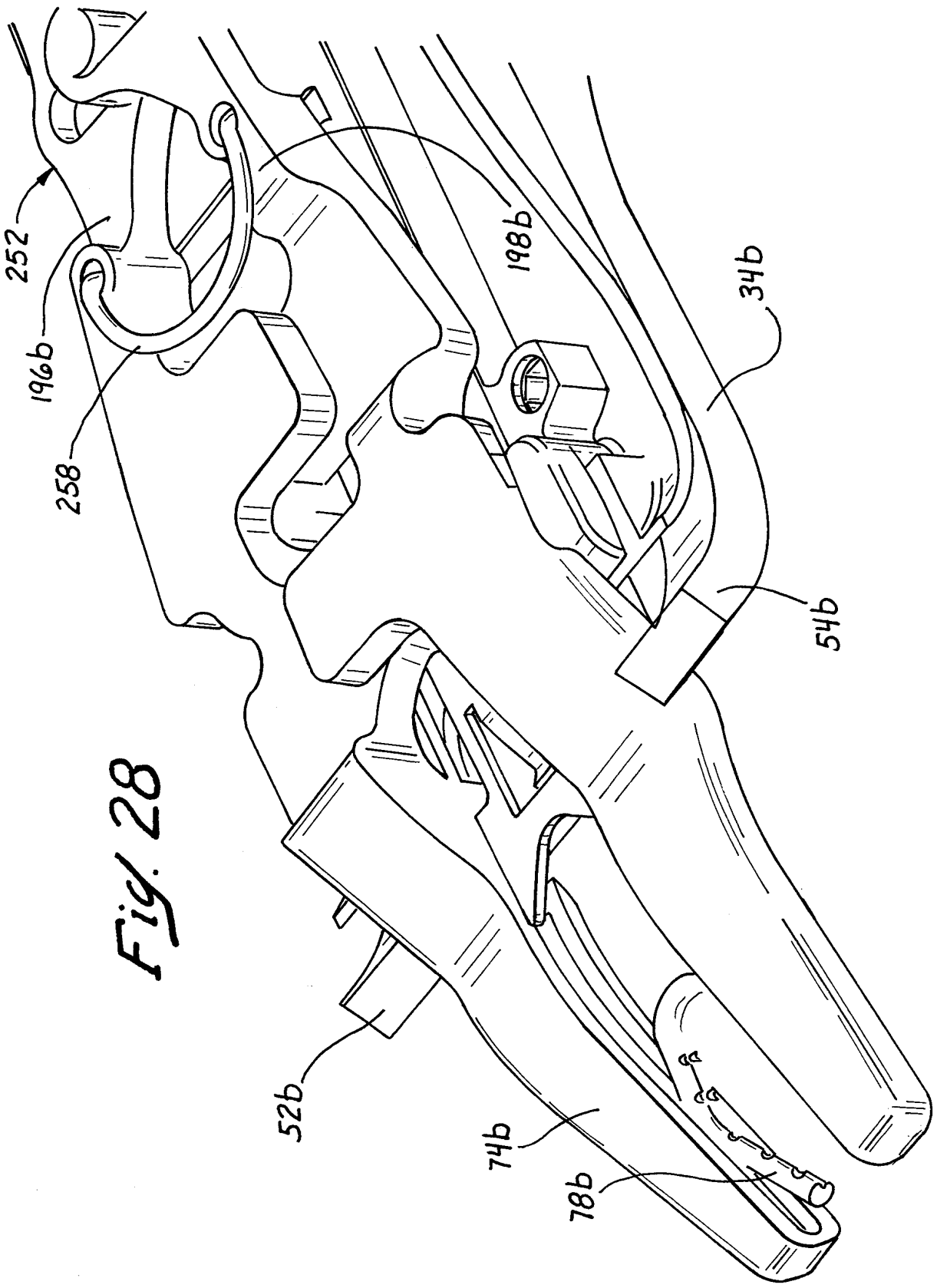

Fig. 28

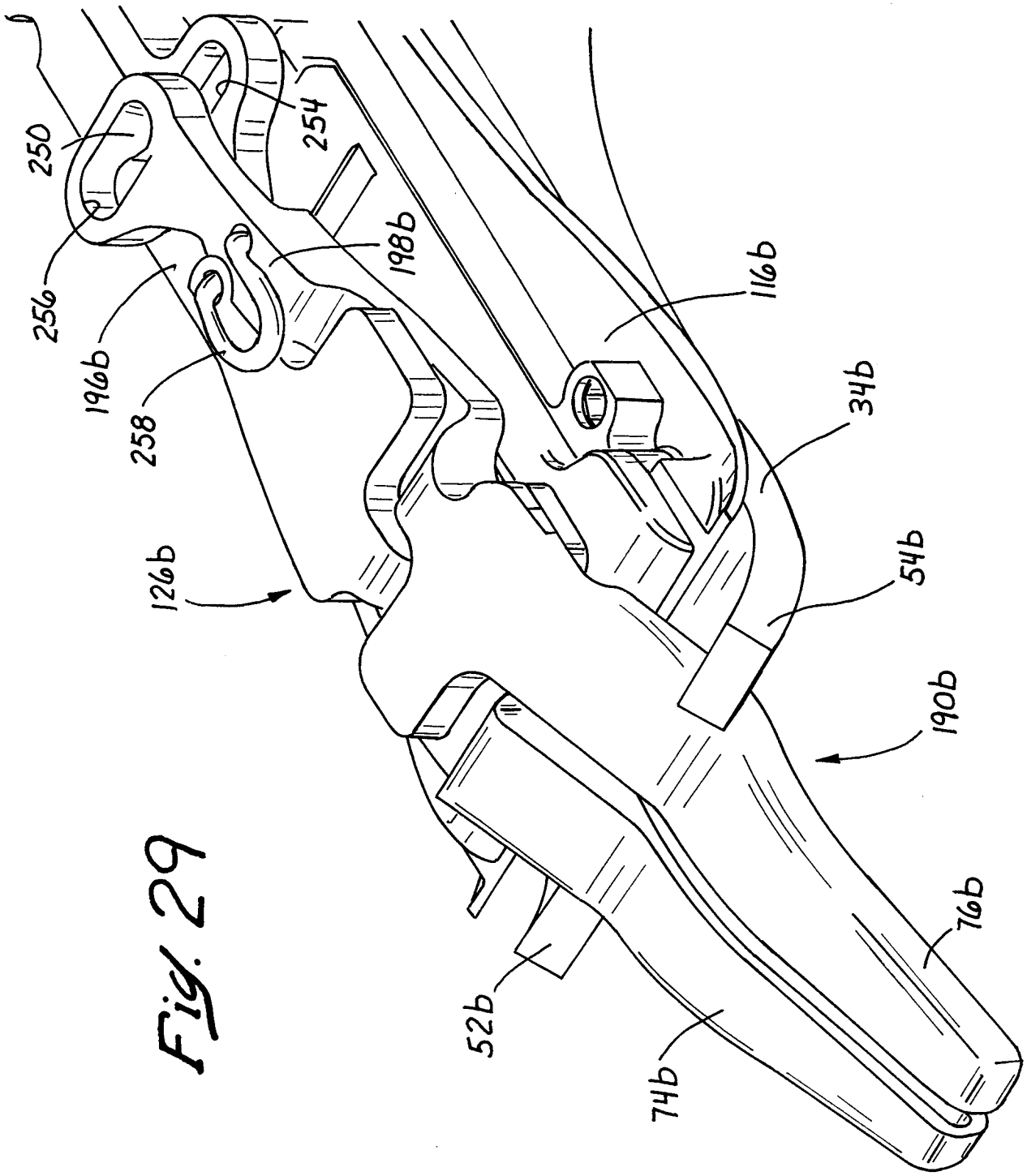

Fig. 29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/01296

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/10
US CL :606/143

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/142, 143, 219, 221

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,166,466 A (JARVIK) 04 September 1979, all figures.	7-18, 24-28, 35-37
X	US 3,082,426 A (MILES) 26 MARCH 1963, all figures.	16-23, 39-45
X	US 5,868,759 A (PEYSER et al.) 09 February 1999, all figures.	10-15
Y	US 5,843,097 A (MAYENBERGER et al.) 01 December 1998, all figures.	24-26, 29-35
X	DES 253,611 E (JARVIK et al.) 04 December 1979, all figures.	54-62

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 08 MAY 2000	Date of mailing of the international search report 08 JUN 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ANTHONY S. KING Telephone No. (703) 306-5962

Form PCT/ISA/210 (second sheet) (July 1998) ★